DARPA-FDA Collaborations and DARPA BCI efforts

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FDA Public Workshop
Brain-Computer Interface Devices for Patients with Paralysis and Amputation

November 21, 2014

The investments to date enable many future paths

Hand Proprioception and Touch Interfaces (HAPTIX)

Revolutionizing Prosthetics

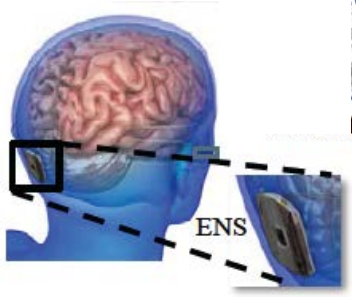
Reliable Neural Interface Technology (RE-NET)

Systems-Based Neurotechnology for Emerging Therapy (SUBNETS)

Movement and Control

Behavior

Memory Recovery



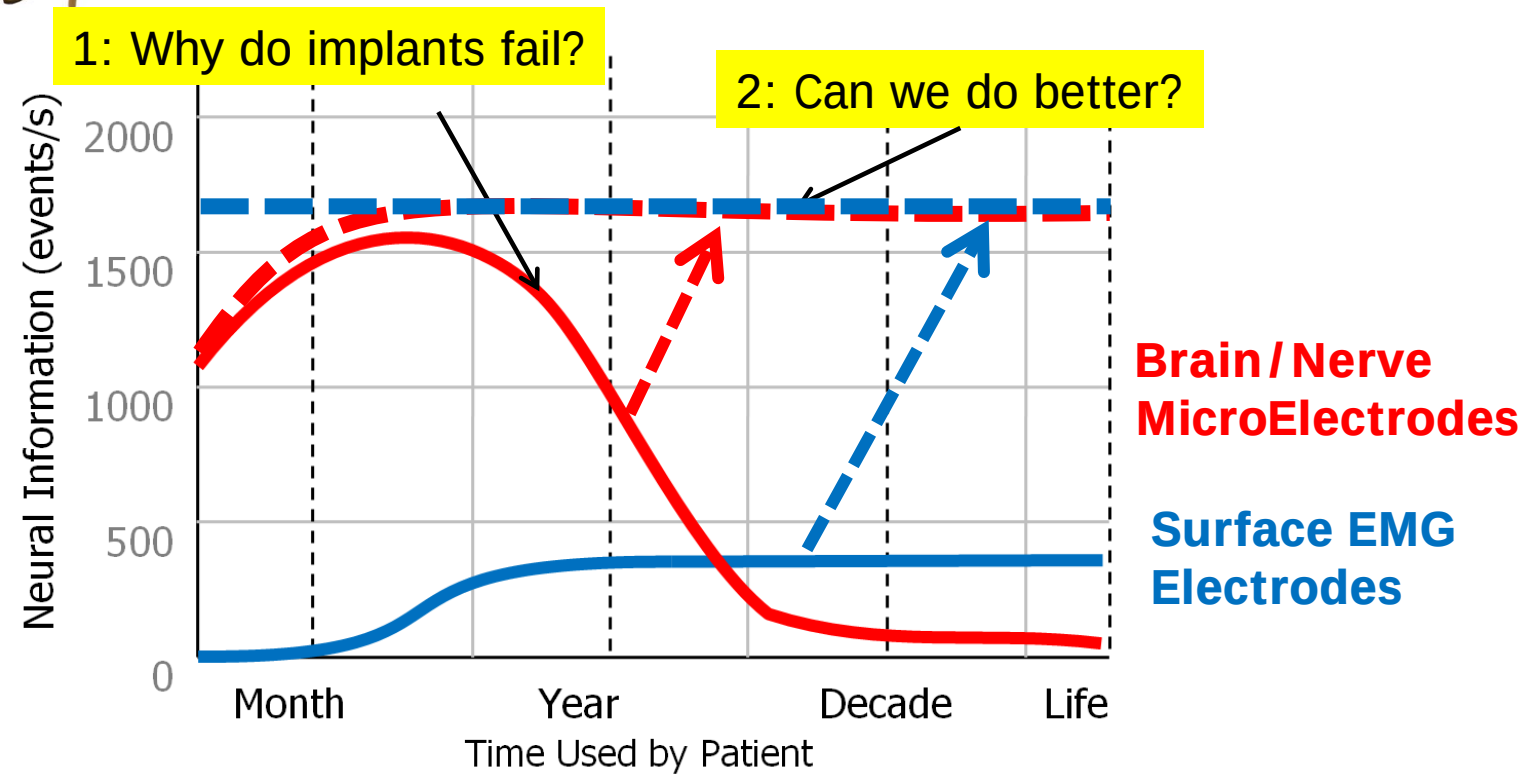
Restoring Active Memory (RAM)

Opportunities:

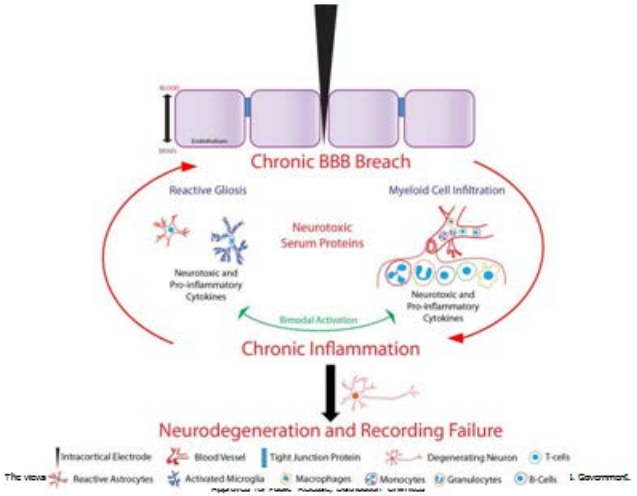
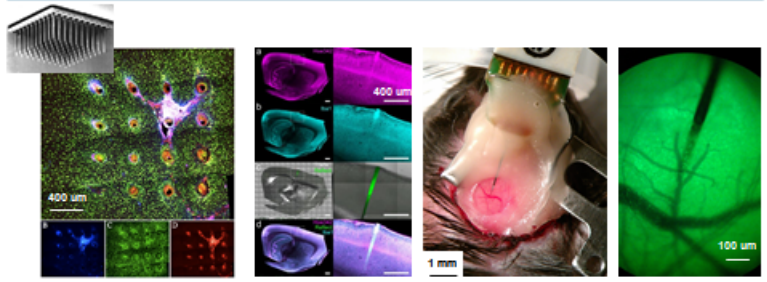
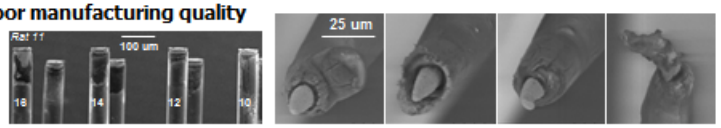
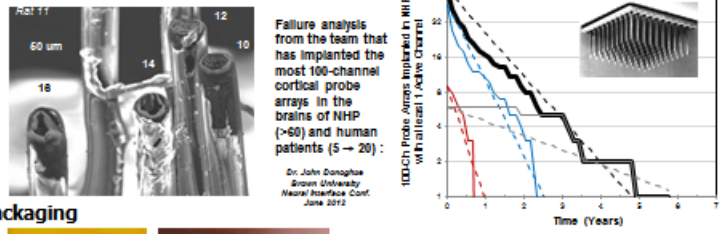
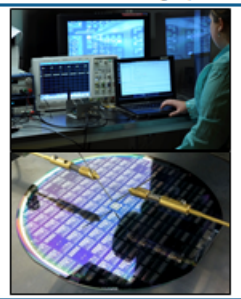
- Physical performance
- Cognitive capabilities
- Noninvasive brain-machine integration

RE-NET Program aimed at increasing lifespan and performance of neural implants

Brain and nerve implants lose signal over time;
Surface EMG provides limited information



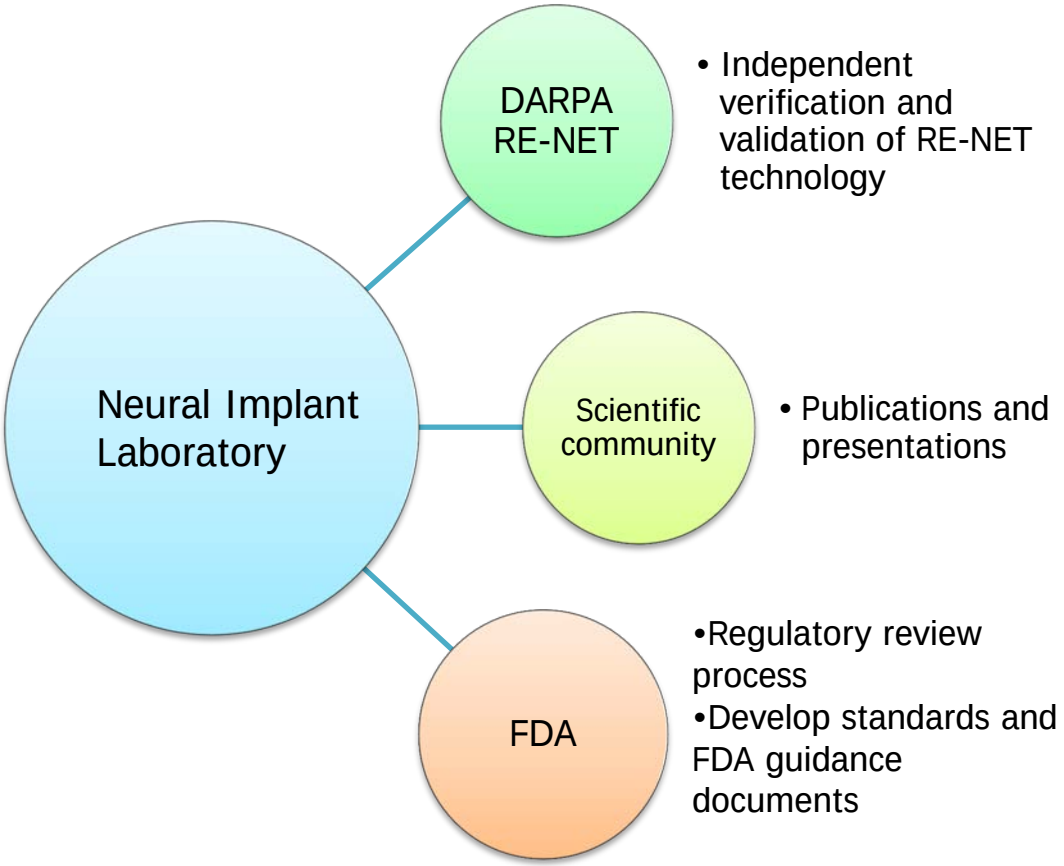
RE-NET Accomplishments

	Discovery	New Capability
Biotic	**BBB Breach and Pro-Inflammatory Cytokines are the Mechanistic Links to Chronic Electrode Failure** 	DARPA HIST: Significance of Biotic Failure Rate  **HIST program created new tools for studying and quantifying tissue changes associated with neural implants** **New HIST methods allow the interaction between implant and tissue to be observed directly for the first time** • both ex vivo (in slices) and in vivo (2 photon) Approved for Public Release, Distribution Unlimited. 15
Abiotic	DARPA HIST: Significance of Abiotic Failure Rate **Poor manufacturing quality**  **Degradation of neural interfaces**  **Packaging**  • **exploiting process-control techniques widely used by the semiconductor manufacturing industry** • **establishing more comprehensive testing standards** • **FDA establishing new accelerated-testing protocol** 13	**RCI AS: Neural-Interface Manufacturing and Reliability Improvement** **NeuroNexus Technologies, Inc. (PI: R. Vetter)** **Overall Project Goal:** Improve statistical process control and manufacturing repeatability. **Approach** • Materials analysis, particle monitoring, wafer probing, statistical analysis, and process control will be used to drive reliability, repeatability, and reproducibility • Fundamental design rules will be tracked and modified based on Design of Experiments (DOE), Response Surface Methodology (RSM), Monte Carlo Simulations, in order to drive DFM and Cp (process capability, a measure of precision) and Cpk (process capability index, a measure of accuracy)  Non Planar Probe (Example) Defective Bond Pad (Example) **Expected Outcome and Metrics** • Probe Planarity: Determine critical process steps leading to stress curl and reduce by film modification and process controls • Impedance: Control and improvement the overall contact and interconnect reliability: (R, C, Z, VBD, CSC, etc.) • Packaging: Bond pad Integrity reliability with reduction of metal pull-off during the assembly process • Metrology: Define critical elements needed to control process parameters to establish baseline performance • Process Control: Characterize process modules with PFMEA analysis, DoE, and RSM to implement SPC systems • In-Line Analysis: In-line electrical and surface analysis to correlate with data sheet requirements to support product integrity

DARPA-FDA program goal

Interagency agreement between DARPA RE-NET program and FDA Center for Devices and Radiological Health (CDRH), Office of Science and Engineering Labs (OSEL), Division of Physics (DP)

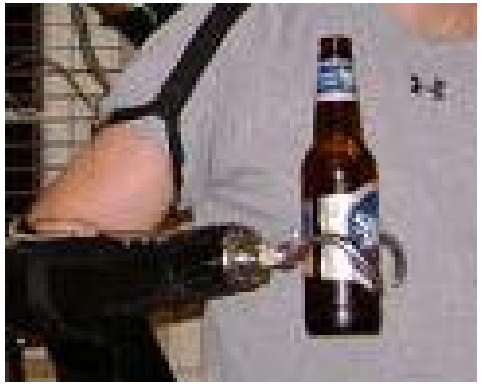
Develop test platforms to evaluate the safety and reliability of neural technology

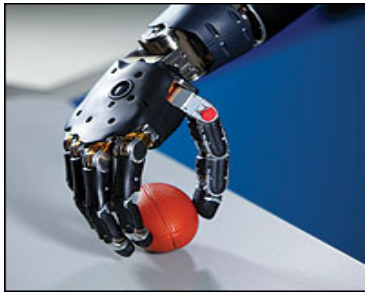


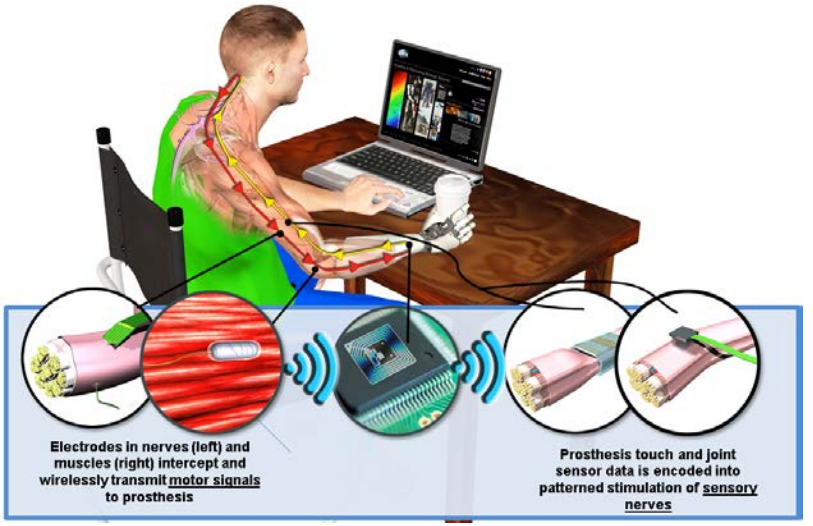
The HAPTIX Vision

Create neural interface technology that enables trans-radial amputees to control and sense state-of-the-art prostheses.

Standard of care → **Revolutionizing Prosthetics** → **HAPTIX program**







Demonstrate complete HAPTIX system(s) in 12+ month early feasibility trials

- 1-3 teams
- Safe, human-ready
- Robust, user-friendly, suitable for home use
- Modular, scalable, multi-functional

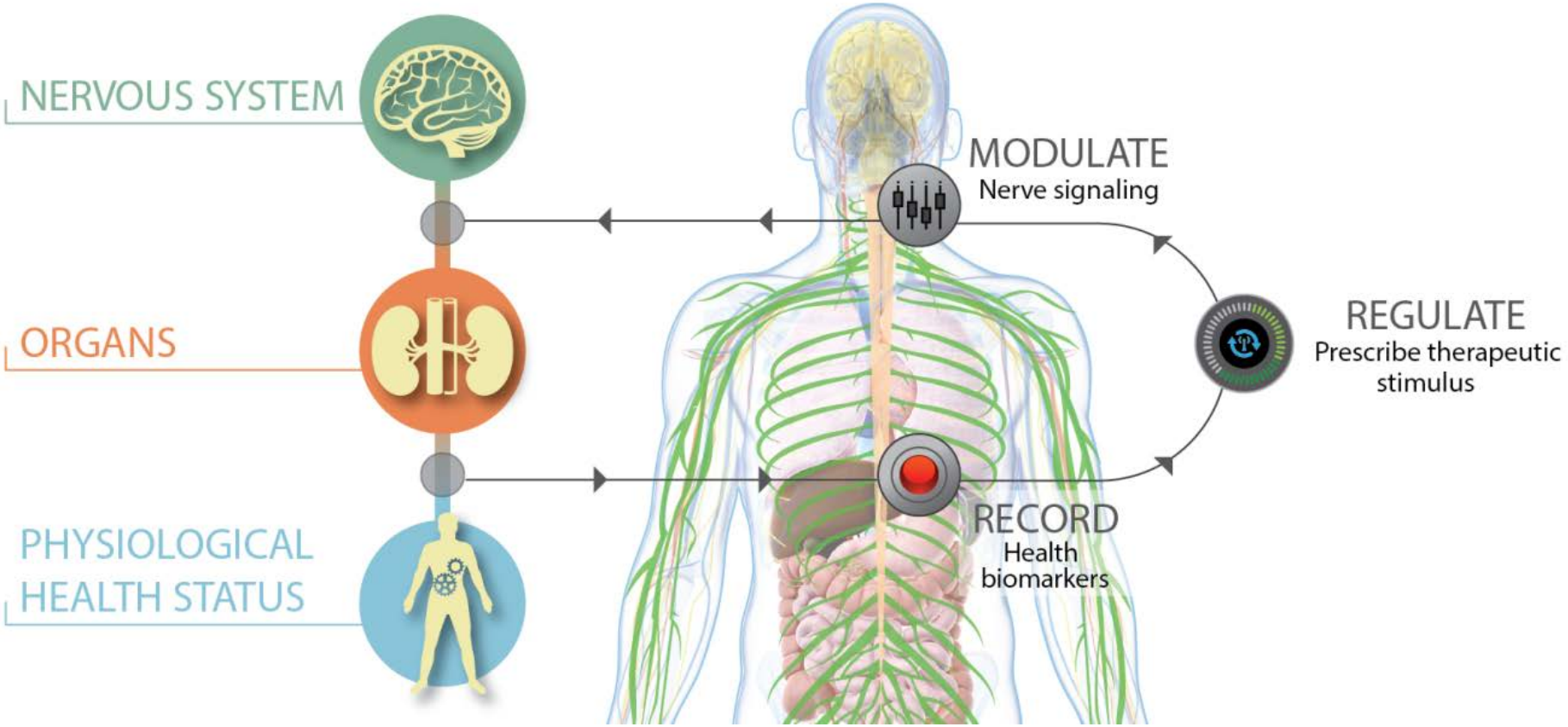
Notional HAPTIX Program Plan

	Phase I (18 months) **Component Level Development**	**Phase II** (30 months) **System Level Integration & Safety Testing**	**Phase III** (12+ months) **First-in-field Human Trials**
TA1 **Electrodes & Algorithms**	**Electrode and algorithm development**	**Signal processing, motor decoding, and sensory encoding algorithm refinement**	**Algorithm optimization**
TA2 **Electronics & Packaging**	**Technology development**	**System integration, packaging, and functional validation**	**System optimization**
TA3 **Human Use Testing**	**Pre-submission processes and outcome metric development**	**Safety testing, IDE processes, and outcome metric validation**	**Conduct human testing**
Advanced Studies	Base period (up to 18 months)	Option period (up to 18 months)	

Down Select ACAs

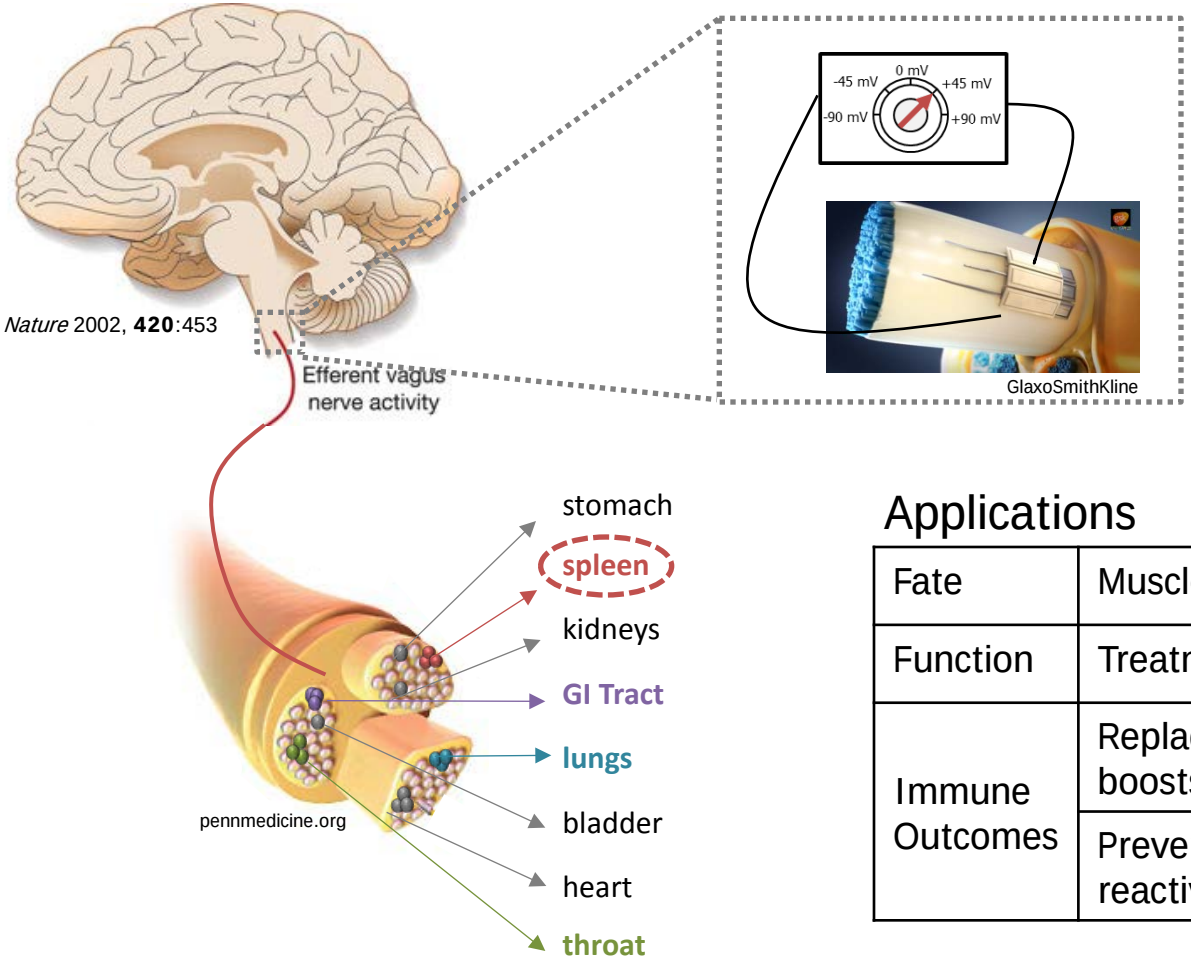
ACAs Down Select

ElectR$_x$ – a new prescription for health



Control electrical signaling in peripheral nerves for desired cellular, organ, and immune outcomes

Goal: Rapid and local measurements, stimulation, and modulation of peripheral nervous system through electricity to impact broad classes of health outcomes



Diverse inputs to tune bioelectric state:

- Electric
- Optical (light)
- Mechanical (ultrasound)
- Chemical (small molecule)
- Location

Applications

Fate	Muscle repair, recovery
Function	Treatment for sepsis
Immune Outcomes	Replace antigen vaccine boosts with electrical boosts
	Prevent cytokine storm/over-reactive immune response