

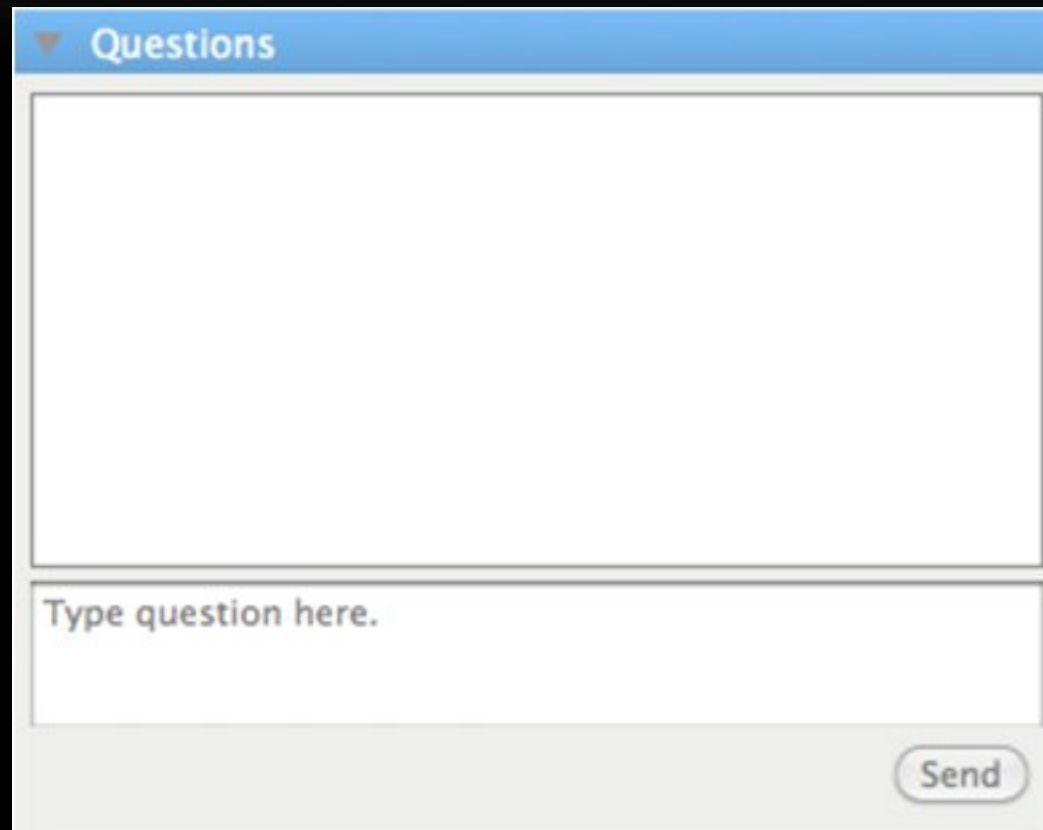
ACCESS TO IMPLANTED PROSTHESIS:

WHAT YOU NEED TO KNOW AND HOW TECHNOLOGY IS USED TO RESTORE FUNCTION

Webinar, July 9, 2014

- Kim Anderson-Erisman PhD, Director Of Education, University Of Miami & Miami Project To Cure Paralysis
- Jennifer French, MBA, Executive Director, Neurotech Network
- Megan Moynahan, MS, Executive Director, Institute For Functional Restoration

HAVE A QUESTION?



Questions

Type question here.

Send



www.theMiamiProject.org

The Miami Project is dedicated to finding more effective treatments and, ultimately, a cure for paralysis resulting from spinal cord injury.



www.NeurotechNetwork.org

***Helping people regain
life thru
neurotechnology***

Focusing on education of and advocacy to access neurotechnology devices, therapies and treatments for people living with impairments, their care-givers and medical professionals.

**INSTITUTE FOR
FUNCTIONAL
RESTORATION**

<http://casemed.case.edu/ifr>

***Committed to restoring
function to people with
spinal cord injury***

The Institute for Functional Restoration has the mission to restore function to people with spinal cord injury by creating a sustainable commercialization model for neuromodulation systems.

DISCLAIMER PAGE

The information presented in this session is not meant to replace the advice from a medical professional. You should consult a health care professional familiar with your specific case, concerns and condition. We highly suggest for you to take information to a trained medical professional familiar with your case to discuss options that are best for you.

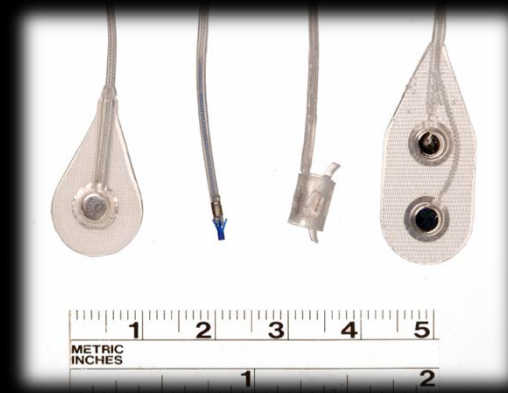
AGENDA

- What are implanted neural prosthetics?
- Therapeutic vs. Prosthetic Application
- Neuro-stimulation & BCI/BMI Applications
- General Pros vs Cons of these systems
- Basics of Clinical Trials
- How do you get plugged in?

WHAT ARE IMPLANTED NEURAL PROSTHETICS?

Neural Prosthesis: A device that connects directly with the nervous system to replace or supplement function.

Implanted Device: A device that surgically implanted into the body. For these applications, electrodes can be applied to a nerve or muscle.



Key Point: Able to restore function for not only acute but chronic conditions

WHAT DOES NEUROTECHNOLOGY OFFER?

FUNCTIONAL RESTORATION TODAY



THERAPEUTIC VS. PROSTHETIC APPLICATION

Therapeutic Application

- Purpose – restore **voluntary** motor control (e.g. hand function) through a **temporary** treatment.
- Therapeutic effect: Restored function that remains after the stimulator has been used for a period of time and then turned off.

Prosthetic Application

- Purpose – **replace** lost neuromuscular function through an intervention.
- Neuroprosthetic effect: The capability of the device, when turned on, to assist a person in performing tasks that the person could not do without the device.

NEUROSTIMULATION APPLICATIONS

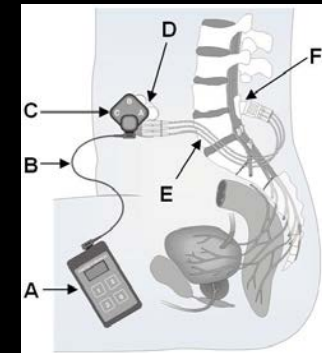


Breathing*

[Neurotech Network: Breathing Fact Sheet](#)



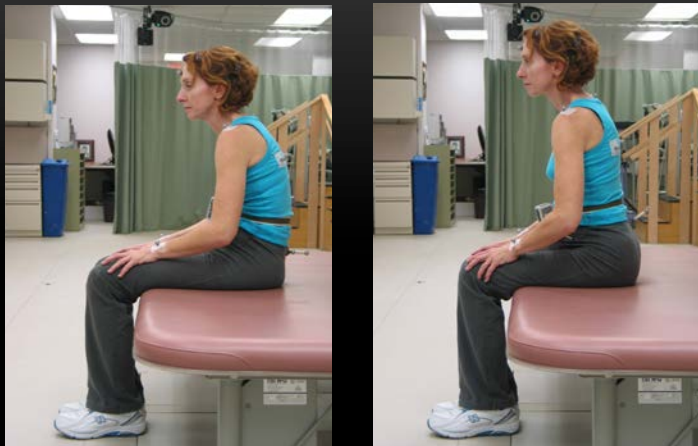
Cough



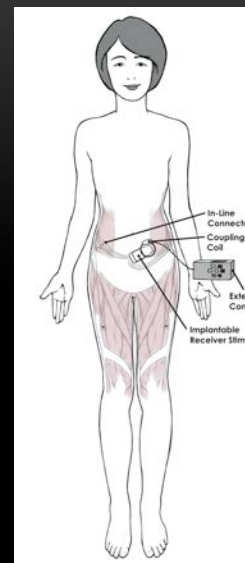
Bladder & Bowel*

[Neurotech Network: Urinary Control Fact Sheet](#)

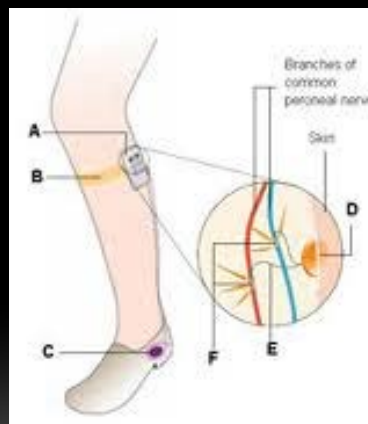
NEUROSTIMULATION APPLICATIONS



Trunk, Posture & Pressure Sore Prevention



Standing & Transfer

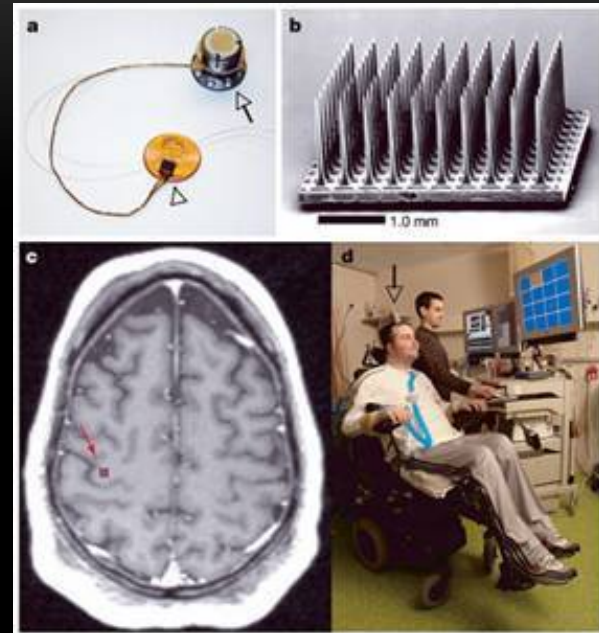


Walking & Drop Foot

Photos courtesy of the Advanced Platform Technology Center, Cleveland FES Center, Finetech Medical

BRAIN COMPUTER INTERFACE/BRAIN MACHINE INTERFACE (DR. HOCHBERG)

- **BRAINGATE 2** - The purpose of this study is to obtain preliminary device safety information and demonstrate proof of principle (feasibility of efficacy) of the ability of people with tetraplegia to control a computer cursor and other assistive devices with their thoughts.
- Boston, MA
- Stanford, CA
- Cleveland, OH
- Providence, RI
- ClinicalTrials.gov Identifier: - NCT00912041



BRAIN COMPUTER INTERFACE/BRAIN MACHINE INTERFACE (DR. BONNINGER - UPMC)

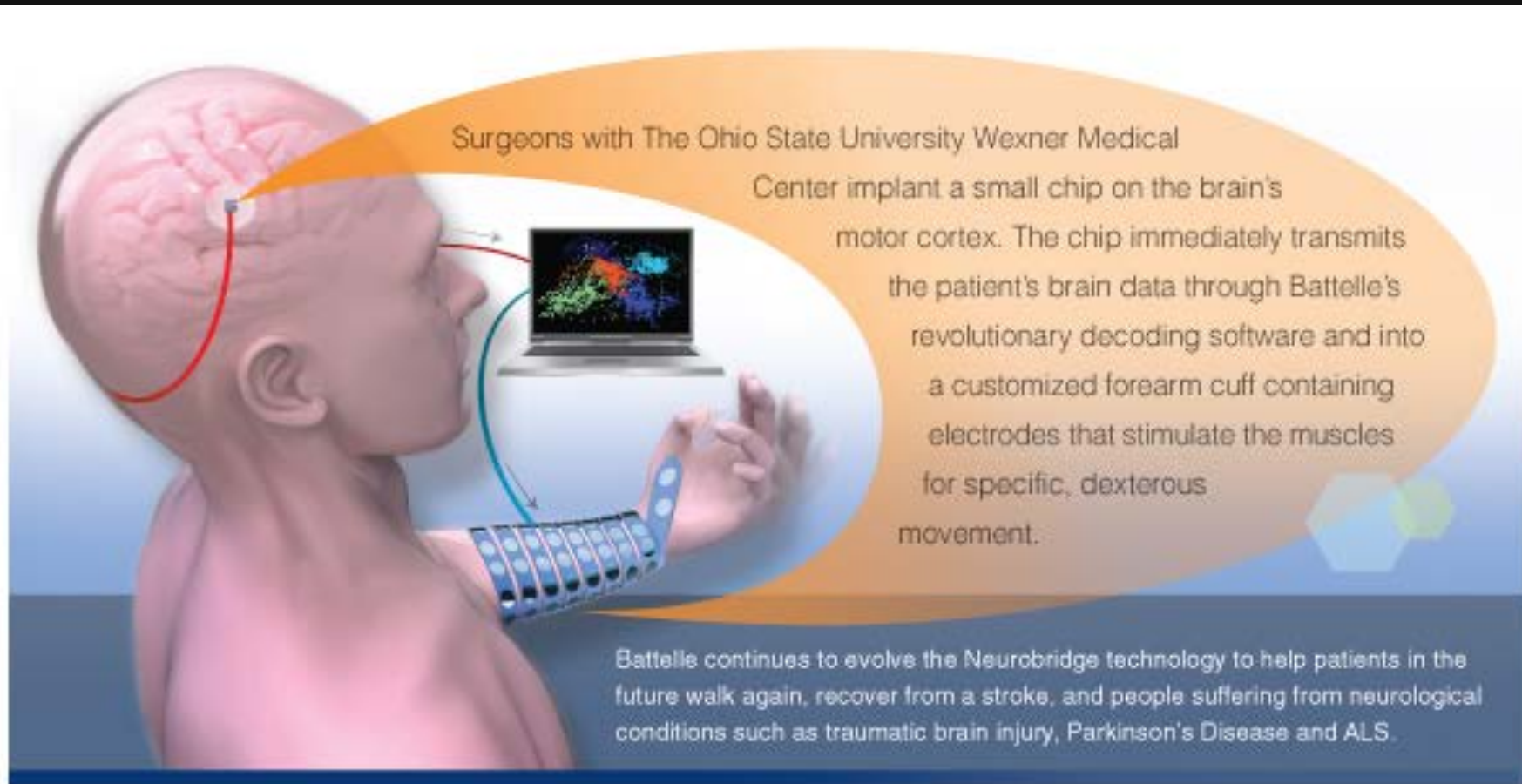
- **PITTSBURGH BCI** - The purpose of these 2 research studies is to demonstrate the safety and efficacy of using two CRS Arrays (microelectrodes) or two NeuroPort arrays (electrodes) for long-term recording of brain motor cortex activity and microstimulation of brain sensory cortex – for control of external devices.
- **Pittsburgh, PA**
- **ClinicalTrials.gov Identifier: - NCT01894802, NCT01364480**



OTHER BCI CONTROLLING EXTERNAL DEVICES

- **Computer – California Institute of Technology/Casa Colinas Rehabilitation Center – NCS; ClinicalTrials.gov Identifier: NCT01958086**
- **Robot – California Institute of Technology/Rancho los Amigos Rehabilitation Center – NPS2; ClinicalTrials.gov Identifier: NCT01964261**

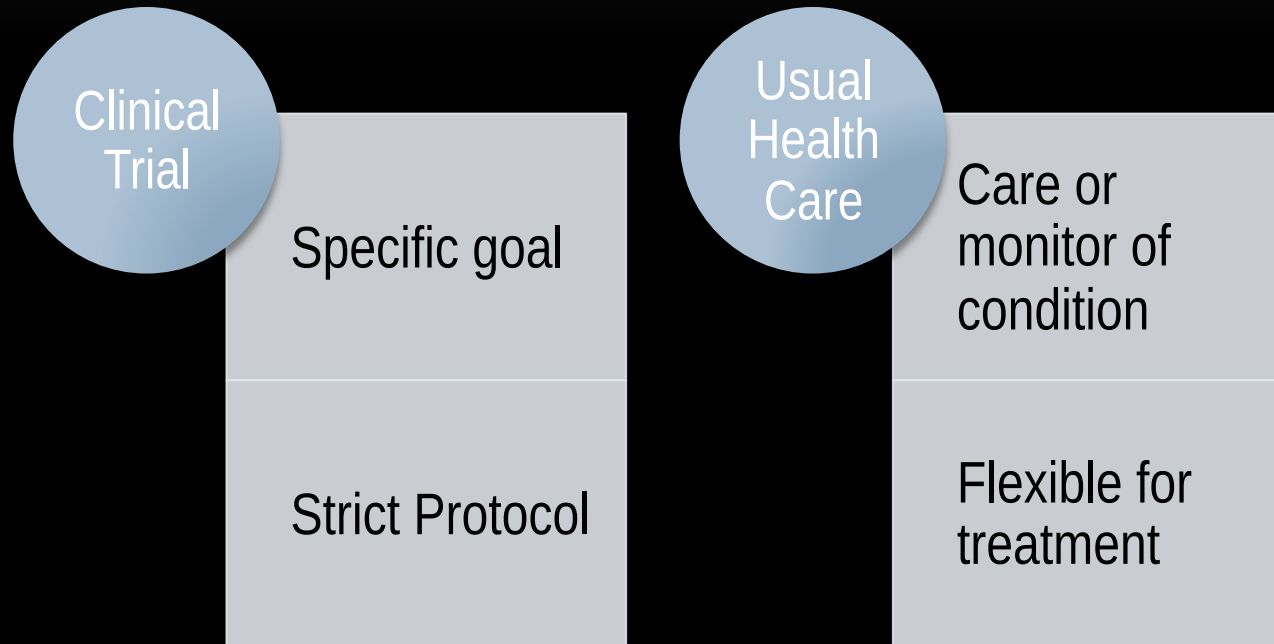
BRAIN MACHINE INTERFACE (DR. REZAI - OSU)



WHY OR WHY NOT GET AN IMPLANTED DEVICE

Why get an Implanted Device	Why Not get an Implanted Device
What else is available for functional restoration?	Fear of interfering with biological therapy in the future.
Found the device early post-injury when still adjusting.	Never knew they existed until 15 yrs post injury.
Ability to use independently.	Increased cost of care to have assistance with device.
Already have other devices implanted.	Already have too many surgical scars, fear of more.
It is portable.	More stuff to carry around: external unit, battery charger, coils, aux. battery, etc.
External appearance is not obtrusive.	External Box is obtrusive.
Limited down time post surgery.	Too busy with work to take the down time or commit to exercise.
Fairly reliable, get what you expect.	How do I know it will meet my expectations?
Aid to decrease incidence of secondary conditions.	Restoring 1 function is not enough benefit to outweigh the down time.

CLINICAL TRIAL IS DIFFERENT FROM HEALTHCARE



WHAT IS A CLINICAL TRIAL?



www.ClinicalTrials.gov

A service of the US National
Institutes
of Health

- Research involving human volunteers (participants) that is intended to add to medical knowledge.
- Lead by a principal investigator
- Research team may include: doctors, nurses, social workers or other health care professionals
- May be sponsored or funded by companies, academic medical centers, voluntary groups, federal agencies and other organizations.

BASICS: CLINICAL STUDY PARTICIPANT

Protocol Information

- 1) Reason for conducting the study
- 2) Who may participate in the study (eligibility criteria)
- 3) Number of Participants needed
- 4) Schedule of tests, procedures, or drugs and dosages
- 5) Length of the study
- 6) What information will be gathered about the participants

source: www.clinicaltrials.gov

SAMPLE QUESTIONS TO ASK

- Anyone interested in participating in a clinical study should know as much as possible about the study and feel comfortable asking the research team questions about the study, the related procedures, and any expenses.
- What is being studied?
- Why do researchers believe the intervention being tested is effective?
- How do the possible risks, side effects, and benefits of this trial compare with those of my current treatment?
- What are my out of pocket costs?
- How will it be determined which intervention is effective?

APPENDIX B: What to ask before taking part in a clinical trial or human study? (your participation checklist)

Note: most of these questions should be answered during the informed consent process

Question	YES	NO	Additional Information
1. Safety			
a. Are there safety risks associated with this experimental treatment?			
b. Could my condition or my health get worse after this experimental treatment?			
c. If so, can you describe the possible risks associated with this experimental treatment?			
2. Possible benefits			
a. Can you describe the possible specific benefits of this experimental treatment?			
b. Can you describe the maximum level of recovery I might see after this treatment?			
c. Can you describe how any potential benefit will be measured?			
3. Clinical trial protocol			
a. Is this study registered as a clinical trial with an appropriate qualified regulatory body?			
b. Can you describe what clinical trial phase this particular human study falls within (Phase 1, 2, or 3) and what is the emphasis of study for this phase of the trial program?			
c. Is there a control group in this study?			
d. Could I be randomly assigned to the control group?			
e. Can you tell me how long I will be assessed for any change in outcome?			
f. Will I be blinded to whether I have received the experimental or control treatment?			
g. Will the investigators and examiners be blind to what treatment I have received?			

Question	YES	NO	Additional Information
4. Payments and costs			
a. Do I have to pay for this treatment?			
b. As a possible participant, are there other costs I have to pay to be involved in this study?			
c. Will my expenses associated with participating in this study be paid (e.g. travel to center for follow-up assessment)?			
5. Participation in Other Trials			
a. Will my participation in this clinical trial limit my participation in other SCI clinical trials?			
b. If I am assigned to the control group and the experimental treatment is subsequently shown to be an effective therapy for my type of SCI by this clinical trial program, will I be eligible to receive this treatment later?			
6. Preclinical or prior clinical evidence			
a. Can you describe the preclinical or prior clinical evidence that indicates this experimental treatment might be beneficial?			
b. Have these findings been independently confirmed by other researchers?			
c. Are there any dissenting opinions and do these arguments have some validity for not going forward with this treatment?			
7. Independent assessment of the treatment and investigator			
a. Can you provide me several names of scientists and clinicians (not involved with this study) who can provide me independent advice about this treatment and your reputation?			

HOW TO GET PLUGGED IN

ClinicalTrials.gov

www.ClinicalTrials.gov

National Library of Medicine & National
Institutes of Health

Possible Clinical Trial Search Terms Plus 'condition' such as SCI, TBI, MS

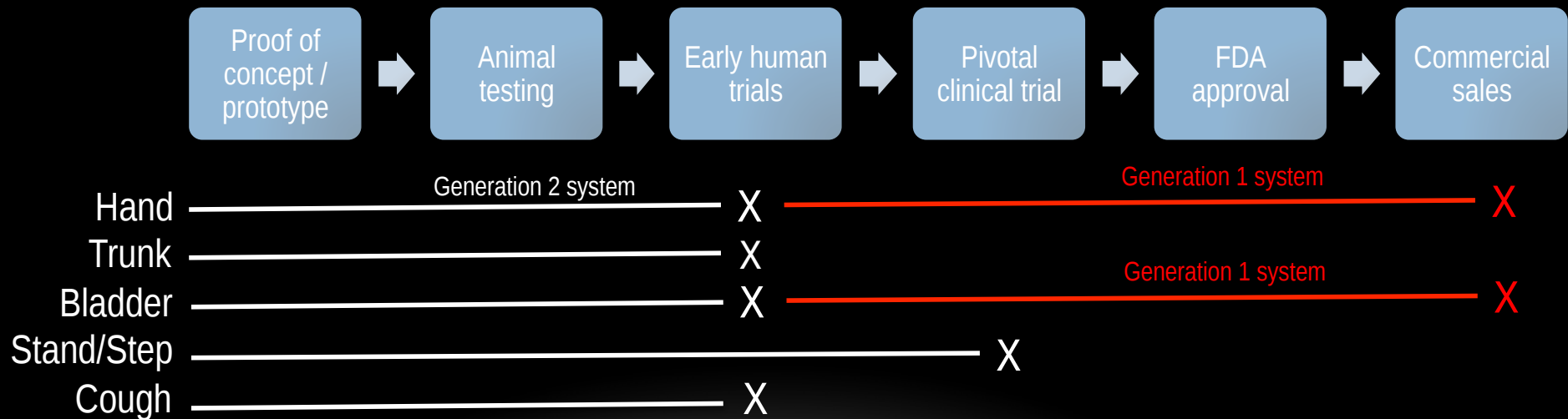
- Implanted prosthesis
- Stimulation
- Neurostimulation
- Neuromodulation

INSTITUTE FOR FUNCTIONAL RESTORATION

- Mission:
 - Restore function to people with spinal cord injury, by creating a sustainable commercialization model for neuromodulation systems.
- Philosophy:
 - How can we help people *today*, while research continues to develop cures for *tomorrow*?
 - How can we learn from history to create a sustainable business model?

INSTITUTE FOR FUNCTIONAL RESTORATION

- Which neuromodulation systems? Anticipated pipeline products include:
 - Hand-grasp, trunk control (reach), bladder continence and voiding, functional standing / stepping, respiratory (cough)

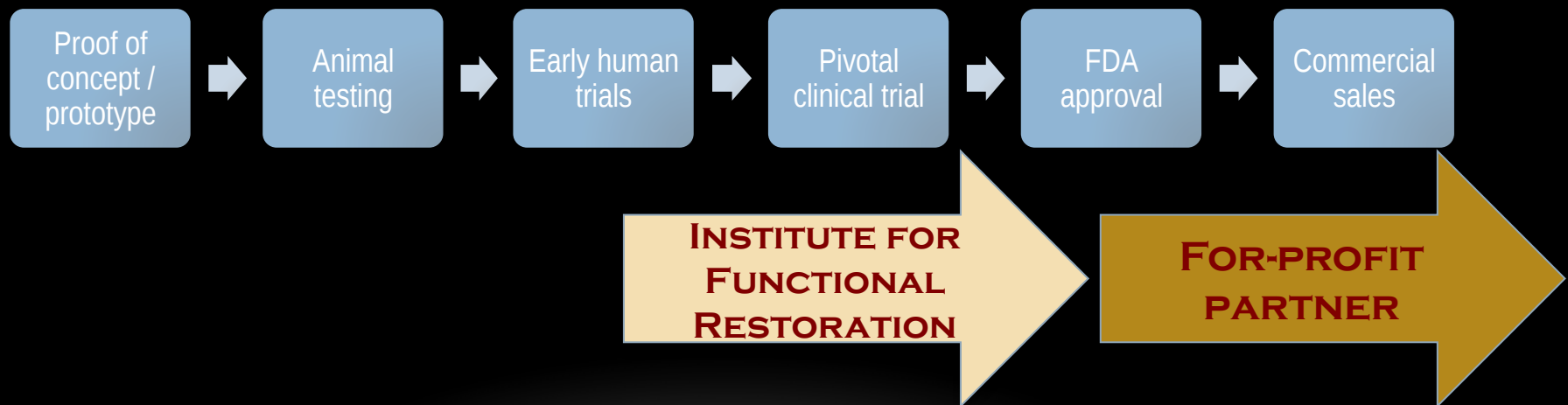


INSTITUTE FOR FUNCTIONAL RESTORATION

- We can learn from history
 - Commercialization of the NeuroControl Freehand system in 1998
 - Great product, failed business model
 - 250+ people with hand function restored, but left without access to follow-up when company went out of business in 2007.
- Good news
 - All the technology hurdles, clinical trials hurdles and FDA approval pathway are already mapped for us.
- Last remaining challenge
 - Figure out how to keep the commercial enterprise going, despite high cost of technology and small market potential.

INSTITUTE FOR FUNCTIONAL RESTORATION

- Solution: For-profit / Non-profit hybrid business model
- Fueled by both philanthropic donations and revenue from sales (eventually)
- Partner together to complete final stages of commercialization



RESOURCES TO LEARN MORE

- Neurotech Network, Spinal Cord Injury Education
http://www.neurotechnetwork.org/education/educate_spinal_cord_injury.php
- Miami Project to Cure Paralysis Education: www.theMiamiProject.org
- Institute for Functional Restoration: <http://casemed.case.edu/ifr>
- TEDx Talk about Implanted Neural Prosthesis by Megan & Jen:
<https://www.youtube.com/watch?v=ykJ0YYhvFDc>
- Cleveland FES Center: <http://fescenter.org/index.php>
- Salisbury FES Research Center: <http://www.salisburyfes.com/index.htm>
- Commercially available devices
 - Breathing: Neurotech Network, Breathing Assistance:
http://www.neurotechnetwork.org/education/educate_breathing.php
 - Avery Biomedical: <http://www.averybiomedical.com/breathing-pacemakers/>
 - AtroTech: <http://www.atrotech.com>
 - Synapse Biomedical: <http://www.synapsebiomedical.com>
 - Bladder & Bowel: Neurotech Network, Urinary Incontinence:
http://www.neurotechnetwork.org/education/educate_urinary_control_resources.php
 - Medtronic Interstim: <http://www.medtronic.com/patients/overactive-bladder/index.htm>
 - Finetech Medical:
<http://finetech-medical.co.uk/Products/BladderControlSystem/tabid/81/language/en-US/Default.aspx>

QUESTIONS?

Kim Anderson-Erisman, PhD
Director of Education
University of Miami
Miami Project to Cure Paralysis
KAnderson3@med.miami.edu
<http://www.theMiamiProject.org>

Jennifer French, MBA
Executive Director
Neurotech Network
jfrench@neurotechnetwork.org
<http://www.neurotechnetwork.org/>

Megan Moynahan, MS
Executive Director
Institute for Functional Restoration
mxm268@case.edu
<http://casemed.case.edu/ifr/>