

FDA Public Workshop - Brain-Computer Interface Devices for Patients with Paralysis and Amputation, November 21, 2014

Goals:

- Fostering an open discussion on the challenges associated with the development of BCI devices
- Obtaining public feedback on scientific, clinical, and regulatory considerations associated with BCI devices for patients with paralysis or amputation



CrossMark

Perspective

Brain–computer interface devices for patients with paralysis and amputation: a meeting report

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Presentations:

FDA regulations

FDA regulatory science

FDA-CMS Parallel review

DARPA BCI programs

State of BCI technology

End user Perspective

Clinical performance metrics

Translation challenges

Industry perspective

Clinical use and metrics

Non-clinical
device testing

Translation and
regulation

Clinical considerations:

- Comprehensive risk and benefit analysis needed
 - including ancillary benefits, such as quality of life improvements.
- User viewpoints should be included in clinical trial design and regulatory framework.
 - Insights throughout the spectrum of time since injury or diagnosis.
- Need for validated functional outcome measures, particularly those that include user perspectives.

Non-clinical device testing:

- Develop a comprehensive test platform that could be used to identify weaknesses in the system
- Guidelines for animal model use and standardized histological assessments
- Develop a publically accessible database of methods and outcomes from previous non-clinical studies
- Establish a goal for device lifetime
- Look to mature technology (pacemakers)

Translation and Regulation:

- Challenges:
 - Regulatory review of devices as entire systems
 - Device classification uncertainty
 - Lack of standards or standardization across industry
- Current practice
 - Prosthetist often uses components from various manufacturers to create a customized patient solution
 - BCI devices are reviewed as an entire clinical system
- One proposed solution:
 - Regulatory review of device 'modules'
 - How would this work? – Possibly through standardization.

Advantages of modular regulatory review

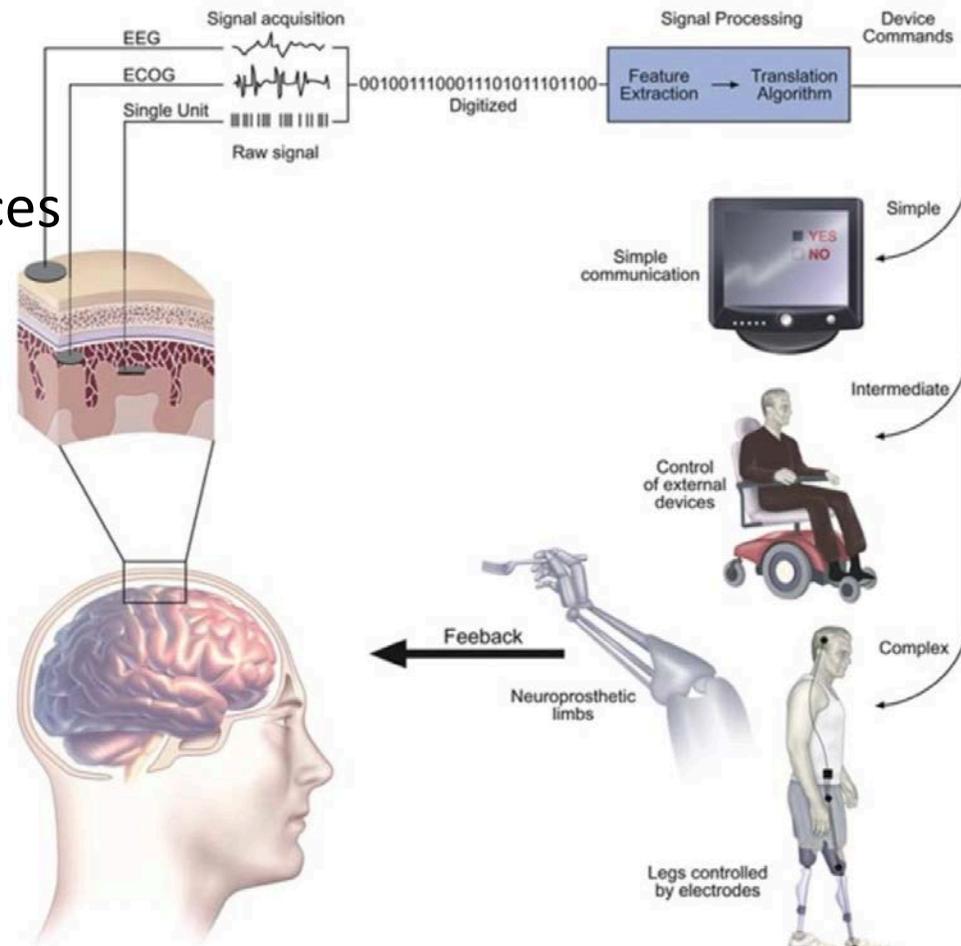
- Reduced development time, cost and time to market
- Increased competitive landscape by allowing the entry of small companies into the market
- Resolves issues involved with device classification
 - reduced clinical and non-clinical testing burden for the manufacturers of lower-risk modules
- Patient benefit – increased customization, better ability to get upgraded or improved components

Concerns and challenges

What are the device 'modules'?

- Electrode interfaces
- Connectors
- Leads

- Surgical methods



- Recording electronics
- Stimulating electronics
- Signal processing

- Effectors (e.g., prosthetic limb, wheelchair, computer, robotic arm, etc)

Challenges to modularity

- How to ensure that the complete system operates **safely and effectively** when individual modules are connected together.
- Defining the **responsibility** for device failure, and appropriate protocols for failure analysis.
- Manufacturers might not find a compelling business case for modularity, and would prefer to manufacture an integrated system.
- Is it too early for modularity?
 - Many devices are still in early development, and modularity might be better considered after key components have first been approved in a complete device system so that components can be built to those standards.

Considerations for use of Standards

- Allow for development of individual, compatible system modules
- For instance, test data set of neural data that each manufacturer could use to test their processing modules.
 - Precedent for this approach may be found in the pacemakers and orthopedic implant device fields.
- Standardizing too early could potentially stifle innovation, if too restrictive.
- Coordination with standards agencies

Future

- FDA guidance document for BCI devices in preparation
 - Once draft guidance is released – opportunity for public comment.