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
Perspective

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

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- 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.