

DRAFT FDA Guidance Document on **Implanted Brain Computer Interface (BCI)** **Devices for Patients with Paralysis or** **Amputation – Non-clinical Testing and** **Clinical Considerations**

Graz Brain-Computer Interface Conference, Workshop 3: Standards for
Neurotechnologies and Brain-Machine Interfacing
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US Public Health Service, Commissioned Corps

Division of Neuromodulation and Physical Medicine Devices (DHT5B)

Office of Neurological and Physical Medicine Devices (OHT5)

Office of Product Evaluation and Quality (OPEQ)

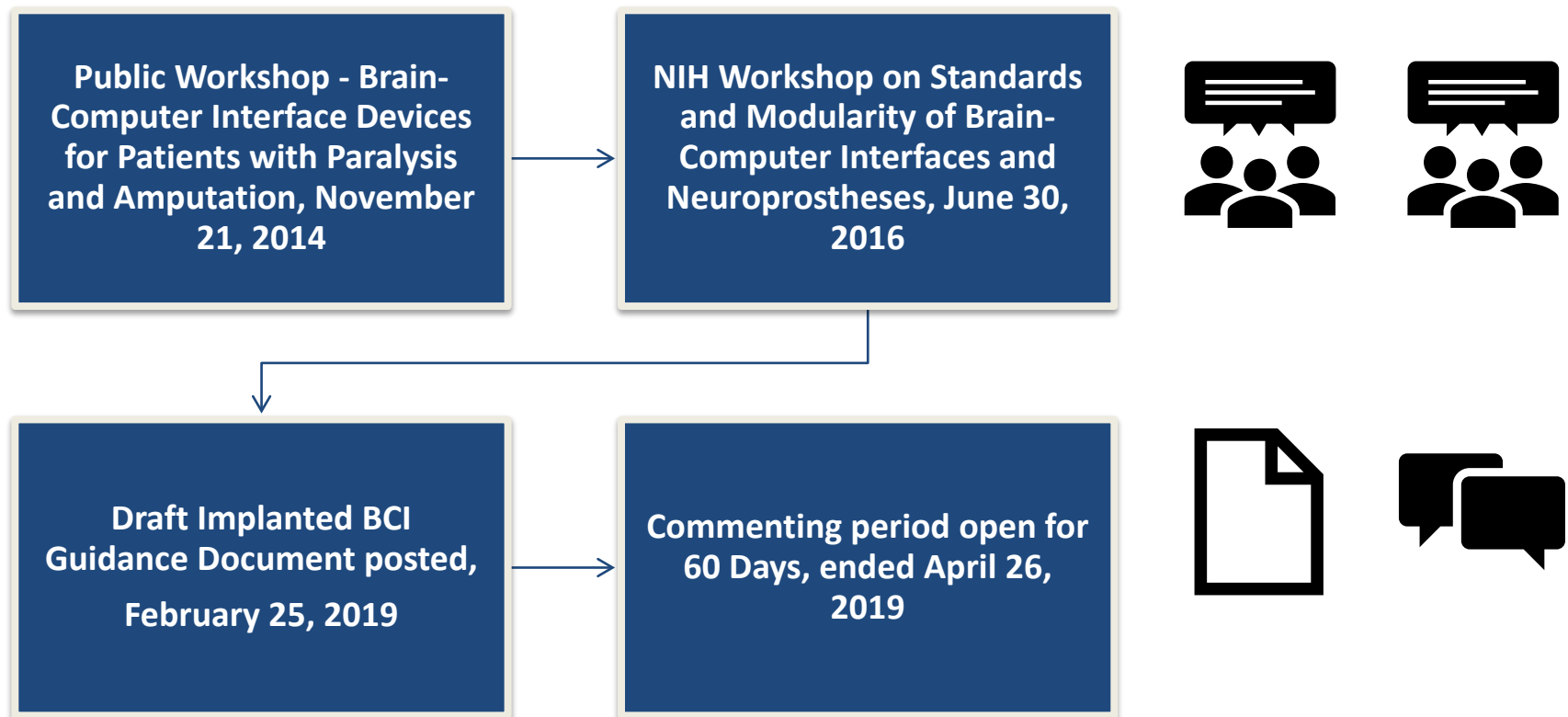
Center for Devices and Radiological Health (CDRH)

Food and Drug Administration (FDA)

Objectives

- **Provide the history of the DRAFT Implanted BCI guidance document**
- **Provide a brief overview of the DRAFT Implanted BCI guidance document sections**
- **Provide a brief overview of:**
 - The FDA Guidance Documents
 - The FDA and Standards

History of DRAFT Implanted BCI Guidance



Scope of the DRAFT Implanted BCI Guidance

Implanted BCI Devices – “neuroprostheses that interface with the central or peripheral nervous system to restore lost motor and/or sensory capabilities in patients with paralysis or amputation”

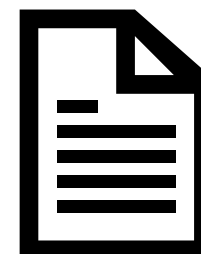
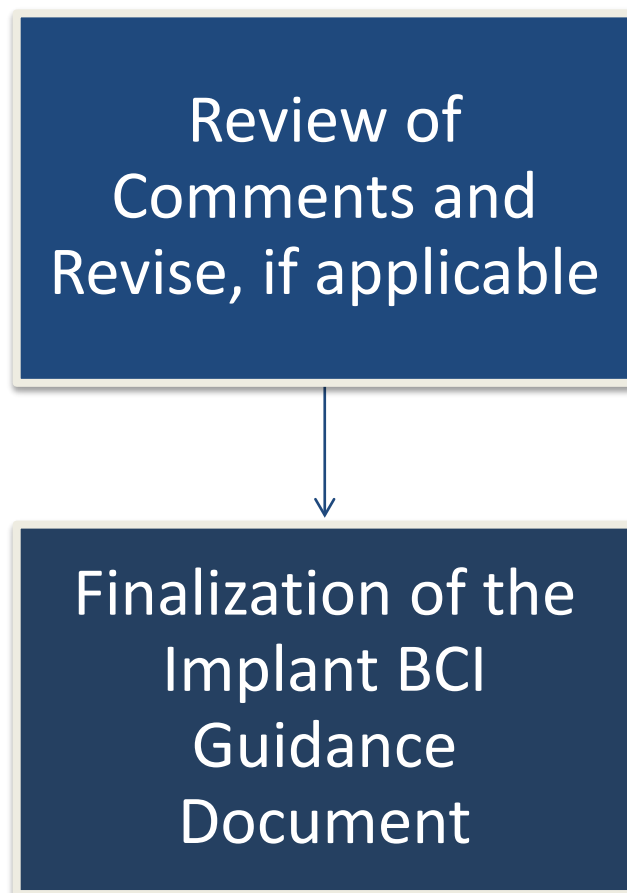
- **Leap-Frog Guidance**
- **Neural Interface**
 - “Central or peripheral nervous system”
- **Intended use/Function**
 - “restore lost motor and/or sensory capabilities”
- **Indications for Use/Patient Population**
 - “Patients with paralysis or amputation”
- **Submission Types**
 - Q-submissions
 - Investigational Device Exemptions
 - Early Feasibility Studies
 - Pivotal Studies

Sections of the DRAFT Implanted BCI Guidance

Overview of Recommendations

Device Description	Cross-cutting Non-clinical Testing	Non-clinical Bench Testing	Animal Testing	Clinical Testing
<ul style="list-style-type: none"> • Device Modules • Device Overview • Key Components • Safety Features • Devices used in conjunction with implanted BCI system 	<ul style="list-style-type: none"> • Software • Biocompatibility • Sterility/Pyrogenicity/Shelf-life and packaging • Electrical Safety and Electromagnetic Compatibility (EMC) • Wireless Technology • Magnetic Resonance (MR) Compatibility 	<ul style="list-style-type: none"> • Risk Analysis • Electrodes • Leads and Connectors • Implanted Casing and Electronics • Output Stimulation Measurements • Output Stimulation Safety • Programmer/Control Unit • Radio Frequency (RF) Transmitter and Receiver • System Level Testing 	<ul style="list-style-type: none"> • General Considerations for Animal Studies <ul style="list-style-type: none"> • Good Laboratory Practices (GLP) • Animal Study Protocols 	<ul style="list-style-type: none"> • Report of Prior Investigations • Clinical Study Considerations <ul style="list-style-type: none"> • Patient Population • Home-use • Investigational Plan

Future Steps for the DRAFT Implanted BCI Guidance



FDA Guidance Documents

- Documents prepared for FDA staff, regulated industry, and the public
- Describe the agency's interpretation of or policy on a regulatory issue
- **DO NOT create or confer any rights for or on any person and do not operate to bind FDA or the public**
- Alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulation, or both

FDA and Standards

- Standards are documents, established by consensus that provides rules, guidelines or characteristics for activities or their results.¹
- Through the Food and Drug Administration Modernization Act of 1997, which modified Section 514(c) of the Medical Device Amendment of 1976, FDA can:
 - Formally recognize consensus standards and to accept a declaration of conformity to a recognized standard
- FDA Uses of standards:
 - Recognize by reference in part or whole
 - Use both national and international standards
 - Can promote international harmonization
 - Reference standards in published guidance documents
 - Encourage conformance to standards to streamline regulatory review and fosters quality
 - Conformance is voluntary, unless a standard is incorporated by reference into regulation

¹ https://www.ansi.org/about_ansi/faqs/faqs?menuid=1

Additional Information Available

- CDRH Learn:
<http://www.fda.gov/Training/CDRHLearn/>
- CDRH Device Advice:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>
- Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices Guidance Document:
<https://www.fda.gov/media/71983/download>
- Standards and Conformity Assessment Program:
<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program>
- CDRHstandardsstaff@fda.hhs.gov
- Guidance Documents (Medical Devices and Radiation-Emitting Products):
<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>
- Q-submission Guidance Document:
<http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm31176.pdf>



Thank You!

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