Feedback - FDA Draft Guidance on Implanted BCIs for Paralysis and Amputation

(*Doc. Ref No. 1500045*)

Commenter: Zach McKinney, PhD

Contact: z.mckinney@ieee.org

Affiliations:

- The BioRobotics Institute, Scuola Superiore Sant'Anna (Pisa, Italy) -- PostDoc Research Fellow
- IEEE Industry Connections Activity (ICA; ID No. IC17-007), *Neurotechnology for Brain-Machine Interfacing* -- User needs area coordinator
- IEEE Working Group P2794 – Reporting Standards for *in vivo* Neural Interface Research (RSNIR) – Chair

Introduction: I have structured my feedback on the FDA Draft Guidance on Implantable Brain-Computer Interfaces (*Doc. Ref No. 1500045*) in accordance with the organization of the 'Neurotech for BMI' industry connections activity (ICA) in which I am participating, which is structured around the five focus areas listed below. For each area, the indicated terms were searched for in the draft guidance, and the document's coverage of the related topics was assessed accordingly. My observations and suggestions are summarized below.

As a member of the neurotechnology standardization groups/initiatives listed above, I would like to thank FDA both for its collective efforts to advance and modernize the state of regulation in the field of BCIs and related neurotechnology with this "leapfrog" Guidance, and for soliciting and weighing industry and public feedback in the preparation of the final Guidance. Indeed, the safe and sustainable fulfillment of clinical needs warrants the consideration of the voices of a diversity of neurotechnology stakeholders, including patients, clinicians, and technology developers alike. Like many of my colleagues, I strongly share FDA's recognition of efficient regulation and Standardization as potential facilitators rather than inhibitors of medical technology development and innovation, by establishing clear, thorough, and publicly visible expectations for the processes and documentation necessary to develop safe and effective medical devices. Moreover, much like the medical device design process itself, I recognize that the formulation of such regulation and Standardization demands iterative dialogue between multiple interested players – as such, I welcome further inquiries from FDA and remain available to provide further clarification of my feedback.

Notation note: brackets denote the completion of words and phrases whose roots were searched, to find multiple related forms of the word.

I. User Needs & Usability [Primary focus of my review]

Search Terms: user need, usab[ility/usable], ease of use, intuit[ive], [intended/conditions/context of] "use" [case], learn, train, user interfac[e/ing], feedback, instruct[ion]

Overall assessment: the coverage of the topic of BCI system user needs, by way of the term "patient preference information" (PPI), is noted and appreciated. To further strengthen the accounting for user needs in the design, clinical validation, and application of BCI systems, I recommend the further incorporation of the following:

- Explicit statement of the link between usability engineering/evaluation, Risk Management (per ISO 14971), and Design Controls (per 21 CFR 820.30), as stated in the FDA Guidance on Human Factors & Usability Engineering
- Explicit use of the phrase "user needs", in line with Design Controls regulation (21 CFR 820.30) and prevalent use throughout clinical literature and industry.

- Identification and definition of "Usability" as a key concept in BCI development and validation, according to IEC 62366 definition
- (For human testing): Identify metrics used for usability evaluation, with specific respect to each of 3 components of Usability identified by the IEC 62366/ISO 9241-11 definition (effectiveness, efficiency, user satisfaction)
    - Provide scientific rationale/justification for use of non-Standard/non-validated metrics (which may well represent the best available for the given BCI system and use case)
- Reference/recommendation of a systematic user-centered design or human factors engineering process, of the type identified in the following Standards:
    - ISO/IEC 62366: Usability Engineering for Medical Devices
    - ISO/IEC 60601-6: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
    - ANSI/AAMI HE 75: Human Factors Engineering – Design of Medical Devices
    - FDA Guidance on Application of Human Factors & Usability Engineering to Medical Devices (Docket No. FDA-2011-D-0469)
    - *ISO 9241-210: Ergonomics of human-system interaction -- Part 210: Human-centred design for interactive systems
    - *ISO 2506n: Common Industry Format – Usability

      *: *not currently FDA-recognized consensus standards*

- Recommendation to describe the process by which user needs were established (e.g. via direct input from prospective or representative users, market research, clinical literature, medical key opinion leaders, etc.), and the metrics and methods to be used for Usability evaluation in the proposed study(s).
- Good!: Section C.vii.3 [Line 1238] on patient preference information (PPI) → further, I recommend the explicit mention/suggestion of including of patient (user) input 'early and often' the device design process, far in advance of clinical trials.
- Recommendation for applicant to identify and distinguish between different types of system user – especially between professional users (trained clinicians, clinical technicians, researchers, etc.) and non-professional users, including the end-user (patient) and non-specialized family or caregivers – all of whom may potentially constitute BCI system users, in different capacities, and in different contexts of use (use cases).
- Clinical protocols should describe methods for user training, for all respective types of potential users identified.
- Detailed description of the intended use cases (Contexts of Use) for which the BCI system is designed and is to be evaluated.

II. Feedback re: other focus areas of the Neurotech for BMI ICA [secondary]

A. Sensors

Search terms: sensor, electrode, transduc[er]

→ Comment: beyond the thorough specification of the sensor properties and performance as indicated by IEC 60601 (et al.), a longer-term goal of this Guidance should be to facilitate the development and emergence of 'gold standard' signal quality parameters for BCI-derived signals of various modalities. Towards this end, it would be helpful for this Guidance to provide more specific recommendations (with reference to existing consensus standards, as applicable) for the sets of

sensors characteristics and properties to be included in the BCI system description, such as those identified with respect to different sensor types in:

Szostak KM, Grand L and Constandinou TG (2017). "Neural Interfaces for Intracortical Recording: Requirements, Fabrication Methods, and Characteristics." *Front. Neurosci*. 11:665. doi: 10.3389/fnins.2017.00665

… Ideally, this guidance should also be written to foresee and accommodate the increasing use of different sensing and stimulation modalities in BCI systems, including optical and ultrasound transducers.

B. Performance and Benchmarking

Search terms: perform[ance], measure, metric, outcome

→ Comment: In addition to the benchmarking of sensor performance, it will be highly valuable (if not fully necessary) for the BCI field to establish a consolidated set of standard performance measures and outcomes, at both the system performance level (re: signal quality, the accuracy of neural decoding, etc.), and at the functional level (task performance accuracy, information transfer rate, etc.). Naturally, the functional level performance metrics are directly pertinent to the evaluation of system Usability (efficiency, effectiveness, and satisfaction)

C. **End Effectors (i.e. Peripheral Devices Controlled)**

Search Terms: peripheral [device, etc.], control, sync[hronization], modular, compatibility, interoperability

- Good!: Section 9 recognition of possibility of modular approach, with different system components from difference manufacturers, and different possible configurations
  - ➔ Recommend including the term "interoperability" in conjunction with "compatibility". …
  - ➔ Also recommend elaborating on the idea of 'criteria for compatibility' [Line 815]: when a BCI system includes (or is designed to facilitate) connection and interoperation with devices from other suppliers, what Standards and other measures are taken to ensure compatibility/ interoperability between different system modules, *and to ensure that such compatibility is maintained in the future*? (E.g. do systems communicate using approved, Standard communication protocols and data streams, or proprietary/ad-hoc protocols that are subject to change in the future?)

D. Data Representation

Relevant Search Terms/Topics: data, format, file, structur[e], process[ing/ed], shar[eability], protocol, security, privacy

➔ This is a vast topic on which I am not an expert and did not specifically address in my review. That said, I would like to note that the creation and widespread adoption of standard neurodata file formats and structures is an essential objective in the field of BCIs and clinical neuroscience, to enable easy aggregation and meta-analysis between different studies, to facilitate a continually improving understanding of the human nervous system – and thus to optimize the safety and effectiveness of BCI systems for pertinent patient populations. Indeed, several large international initiatives such as NeuroData Without Borders, the Neuroimaging Data Model (NIDM), and Brain Imaging Data Structure (BIDS) hold this goal in common.

III. Additional/Misc. General Comments

- GOOD!: Mention of referenced FDA consensus standards in introduction [Line 51]
  - ➔ Further recommendation: cite additional consensus standards throughout the document, where relevant, including, e.g.:
    - Usability and user-centered design standards (as noted above)
    - SW Standards - ISO Series 25000
    - ISO 13485: Quality Management Medical devices -- Quality management systems -- Requirements for regulatory purposes
- Section 2.9 (Surgical approach) [Line 1010] and/or C.vi [Line 1211] – add specificity about electrode/sensor positioning methods and repeatability (how is target electrode site identified and the electrode(s) placed? … is there a functional component of the implantation procedure?)

Many thanks again to the Agency for your collective consideration and collaboration,

Zach McKinney, PhD