Heeding BCI Users' Needs and Preferences in Regulatory Decision-Making: Where Do We stand? What Next?

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Introduction

- As a novel means to help functionally diverse individuals to replace, restore or enhance their bodily and mental functions, brain-computer interfaces (BCIs) play a complementary role in enabling individuals to exercise their civil rights e.g. right to vote becoming exercisable by a locked-in person, enjoy their human rights and personality rights, thus making it possible for the law to recognize and address them as legal persons with full capacity.
- It may also be the case that the user identifies himself/herself with the BCI, considers it as a part of his/her body or self, and has an interest in it as the device allows him/her to participate in the society or just be/feel like himself/herself.
- For these reasons, the needs, perspectives and preferences of actual users of these devices should be considered at least as valuable as the inputs from engineers, developers and experts like physicians and clinicians in all phases of the product lifecycle, and pre and post market assessments.
- This paradigm shift will ultimately result in cost reduction, acceleration of product development and quality improvement, which will be beneficial for all stakeholders in the end.
- Opportunely, just like the increasingly recognized value of user experience as input into the design and regulatory decision-making of various consumer products, in healthcare policy and research too, there is a trend of efforts to bring the patient's voice and perspective into clinical trial design, several phases of product lifecycle, pre-market authorization, post-market surveillance, labelling and standardization of medical devices.
- This study is an effort to illustrate how patient perspectives have begun to inform regulatory-decision-making, by providing examples from international consensus standards, best-practice guidelines and standardization efforts of medical device regulatory bodies of jurisdictions like the USA, Canada and the European Union, with a special emphasis on BCIs, and to address the inadequacies that need to be overcome and gaps that need to be filled in particular in the field of standardization of embedding patient voice in product lifecycle and regulatory decision-making.

How does user experience and patient input inform normative outputs?

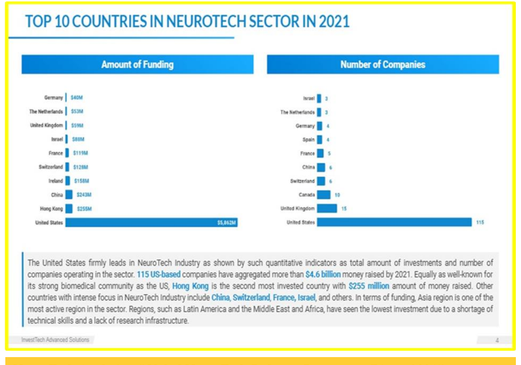
- to inform design - user centered design
- to inform clinical practice - patient centered clinical trial design and treatment
- to inform regulations and standards

Why is embedding of user needs/perspectives/experience important in BCIs?

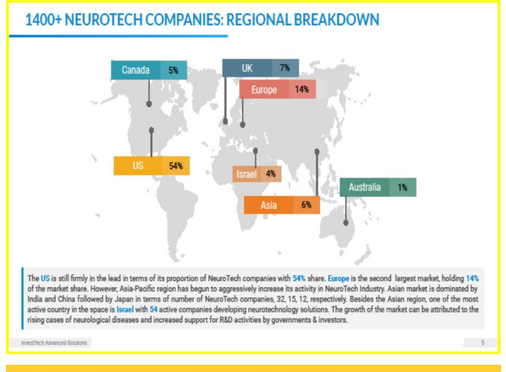
- Useful benefit-risk balancing results. E.g. to evade Collingridge dilemma. So a bottom-up approach is optimal.
- Different points of view of users should also be taken into account in the name of pluralism and democratic, deliberative technology development
- Nothing about us without us: rights claims by disability studies, disability maker movement.
- A pragmatist lens to see user as an expert of his experience. E.g. democratic division of labor espoused by Dewey, in which everyone is an expert in some area or another.
- Evidence-based medicine.
- Due to important interests of the person in them, many of these technologies may be subject of claims of part of body or person. Identity/personhood constitution. So persons should have a right of say on them. (e.g. devices enabling one to vote or communicate or to just sense the outer-world, hippocampal memory prosthetics, those that are vital and so on)

Is there a legal basis/requirement to study user/patient experience/perspective in Medical Device (MD) regulations and standards?

- There is a trend in embedding user and patient voice in several fields, patient rights activism, emphasis on user centered design in many products, but medical products has been slow to follow mainly due to safety security concerns and the power dynamics giving the word to experts.
- Is there a legal basis for these efforts? What is the outlook in the field of medical devices and neurotech? Our research demonstrated that there are quite a few regulatory efforts in the US. Why?
- The global figures justifies the need for regulation. The more the companies, and research and manufacture practices, the more the need. Thus, our research is based mainly on US regulations.



NeuroTech Analytics, "Global NeuroTech Industry Investment Digest 2021" https://www.neurotech.com/analytics



NeuroTech Analytics, " Neurotech Industry Q4-2021" https://www.neurotech.com/analytics

Legal Basis of Patient Input Recommendations in FDA regulations:

- Code of Federal Regulations Title 21 (21 CFR 820.30) – governing quality system regulation of medical devices, in particular incorporating user/patient input into the design process
- Food and Drug Administration Safety and Innovation Act amended Federal Food, Drug, and Cosmetic Act §569C (21 U.S.C. 360bbb-8c(a)) and introduced patient participation in medical product discussions

FDA Guidance Docs involving Recommendations to Include Patient Input in Medical Device Product Life-cycle

- ✓ Initially: Patient representative on advisory panels
- ✓ 2009 FDA Guidance Document "Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims"
- ✓ 2012 FDA guidance "Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications"
- ✓ 2015 MDIC Patient Centered Benefit-Risk (PCBR) Framework
- ✓ 2016 FDA Guidance Document "Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions"
- ✓ 2016 FDA Guidance Document "Patient Preference Information – Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling"
- ✓ 2016 FDA Guidance Document "Applying Human Factors and Usability Engineering to Medical Devices"
- ✓ 2017 FDA Guidance Document "Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions (IDEs)"
- ✓ 2017 FDA Guidance Document "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices"
- ✓ 2018 FDA Guidance Document "Breakthrough Devices Program"
- ✓ 2018 FDA Guidance Document "Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics"
- ✓ 2019 FDA Guidance Document "Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications"
- ✓ 2019 FDA Guidance Document "Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions"
- ✓ 2021 Establishment of the Patient Engagement Advisory Committee to advise FDA re medical devices
- ✓ 2021 FDA Guidance Document "Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation - Non-clinical Testing and Clinical Considerations
- ✓ 2022 FDA Guidance Document "Principles for Selecting, Developing, Modifying, and Adapting Patient Reported Outcome Instruments for Use in Medical Device Evaluation"
- ✓ 2022 FDA Guidance Document "Patient Engagement in the Design and Conduct of Medical Device Clinical Studies"

Other Jurisdictions

Following FDA initiatives, rather lagging behind.

Canada

- Strategy for Patient-Oriented Research (SPOR) - Patient Engagement Framework
- Patient Engagement (PE) Framework
- Health Quality Ontario Patient Partnering
- Mainly on development and approval of drugs
- Medical Devices Directorate established in 2020
- Medical Devices Action Plan involves stakeholder meetings and engagement activities
- Applies global standards (ISO)

EU

- EU Medical Device Regulation –mostly re usability, no language placing user as a stakeholder (e.g. devices must be suitable for their intended purpose, requires manufacturers to have a risk management system.)
- Innovative Health Initiative (IHI)'s (formerly IMI) PREFERENCE (Patient Preferences in Benefit–Risk Assessments during the Medical Product Lifecycle) Project – issued recommendations re how to incorporate PP into medical product lifecycle to support development of guidelines for industry, Regulatory Authorities and HTA bodies.

Medical Device Human Factors/Usability Standards

- IEC 62366-1:2015, Medical Devices Part 1: Application of Usability Engineering to Medical Devices
- IEC TR 62366-2:2016, Medical Devices Part 2: Application of Usability Engineering to Medical Devices
- IEC 60601-1-6:2010+AMD1:2013 CSV, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- ISO 14971:2019, Medical devices – Application of risk management to medical devices
- ISO 9241-210: Ergonomics of human-system interaction - Part 210: Human-centred design for interactive systems (standardized UCD)
- ANSI/AAMI/IEC 62366-1:2015, Medical Devices Part 1: Application of Usability Engineering to Medical Devices
- ANSI/AAMI HE75:2009/(R)2018, Human factors engineering—Design of medical devices
- AAMI TIR59:2017, Integrating human factors into design controls
- AAMI TIR 51:2014/(R)2017, Human factors engineering - Guidance for contextual inquiry
- AAMI TIR 50:2014(R)2017, Post-market surveillance of use error management
- AAMI TIR49:2013, Design of training and instructional materials for medical devices used in non-clinical environments
- ISO/IEC 25000 series (defines System and Software Quality Requirements and Evaluation (SQuARE), with specific user needs-related standards including ISO/IEC 25022 (Measurement of quality in use) and ISO/IEC 25066 (Common industry Format for Usability—Evaluation Reports) (for software component)
- These are not specific to neurotechnologies, so there is a standardization gap.

Inclusive Innovation

- EU Horizon 2020 program (Responsible Research and Innovation (RRI)),
- OECD Recommendation on Responsible Innovation in Neurotechnology,
- Several other initiatives for inclusive, participatory technology policies, multistakeholder, upstream directed anticipatory regulation

Future Projections

Increasing efforts to incorporate patient input in design and regulatory decision-making of MD and in particular clinical trial design and practices for BCIs/neurotechnologies, led by the USA and followed by other jurisdictions.

Increasing patient activism and disability studies engagement in the academy.

Increasing value attached to evidence-based medicine and incorporating real world evidence (RWE) in MD lifecycle.

Increasing tendency to consider user as the expert of his/her own experience.

Increasing growth and innovation in the neurotechnologies/BCI market.

Thus, we project that these practices will solidify and become commonly accepted practices, which may then turn into mandatory provisions rather than voluntary recommendations.

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