Reporting Standards for *in vivo* Neural Interface Research (RSNIR) to Accelerate Interoperability, Clinical Integration, and Commercialization of NeuroTechnologies

Graz BCI Conference 2019

Workshop on Standards for NeuroTechnologies and Brain-Machine Interfacing

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Overview (Objectives)

- **WHY Standardize?**
  - ➢ Rationale for standardization of neural interface research reporting
- **WHAT to Standardize (next)?**
  - ➢ Intro and scope of IEEE Working Group P2794 (RSNIR)
- **WHO Are we?**
  - ➢ WG P2794 membership and constitution
- **HOW are we doing it?**
  - ➢ WG Strategy and Segmentation
  - ➢ Current & Upcoming Activity
  - ➢ *Input: How can you contribute?*

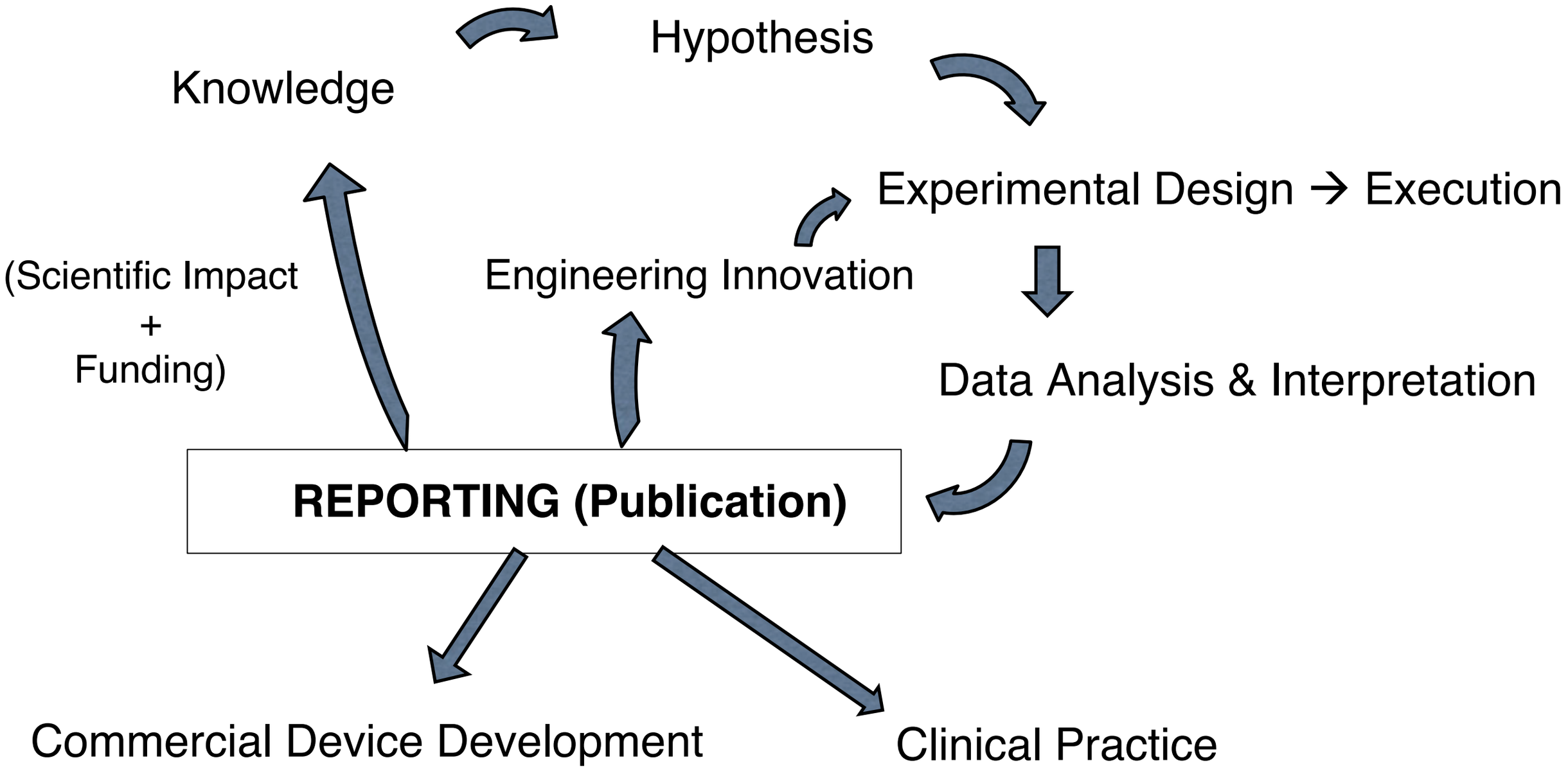
WHY Standardize?

…what's the need? … what's the value?

→ to enable INTEGRATION!

1. **Interoperability (Functional Integration)**
   - Ecosystem of "plug & play" devices and systems
   - Functional/integrative neuroscience
   - Multimodal rehabilitation
2. **Assimilation (Information Integration)**
   - Personalized & evidence-based medicine
   - Systems neuroscience & multimodal rehab i
3. **Translation (Clinical & Commercial Integration)**
   - Demonstration of *value* via rigorous validation and reporting

Innovative Research & Development Process



WHY Standardize *Reporting*?

→ **High-quality, high-impact publications are a primary de facto objective for neurotechnology researchers**

→ **Rigorous experimentation and reporting is the way to validate, communicate, and translate the *value of neurotechnology***

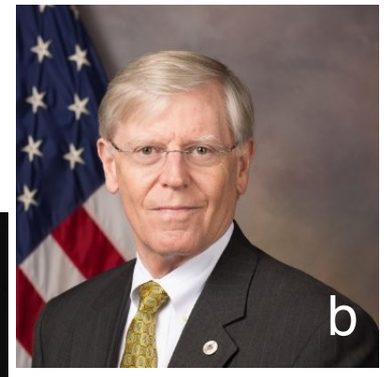
- To scientific reviewers
- To funding agencies
- To (medical) device regulators
- To healthcare payers
- To device users (doctors, clinicians, patients)

→ **Therefore, reporting standards can establish a broad incentive scheme for both neurotech researchers and device developers**

- For researchers: via scientific publication review
- For commercial developers: via regulatory body review

Intro: IEEE Working Group P2794:
Reporting Standards for *in vivo* Neural Interface Research (RSNIR)

- **WG P2794 Officers**
  - a. **Chair:** Zach McKinney – Scuola Superiore Sant'Anna (z.mckinney@ieee.org)
  - b. **Vice Chairs:** Dennis McBride – NeuroRx, Source America
    Calvin Eiber – University of Melbourne
  - c. **Secretary:** Yu Yuan – Senses Global Labs & Ventures
- **Sponsoring Committee Representative:**
  - d. Carole Carey – C3-Carey Consultants, EMB/Stds Com
- **IEEE Support Staff**
  - e. Tom Thompson



WG P2794 Affiliation

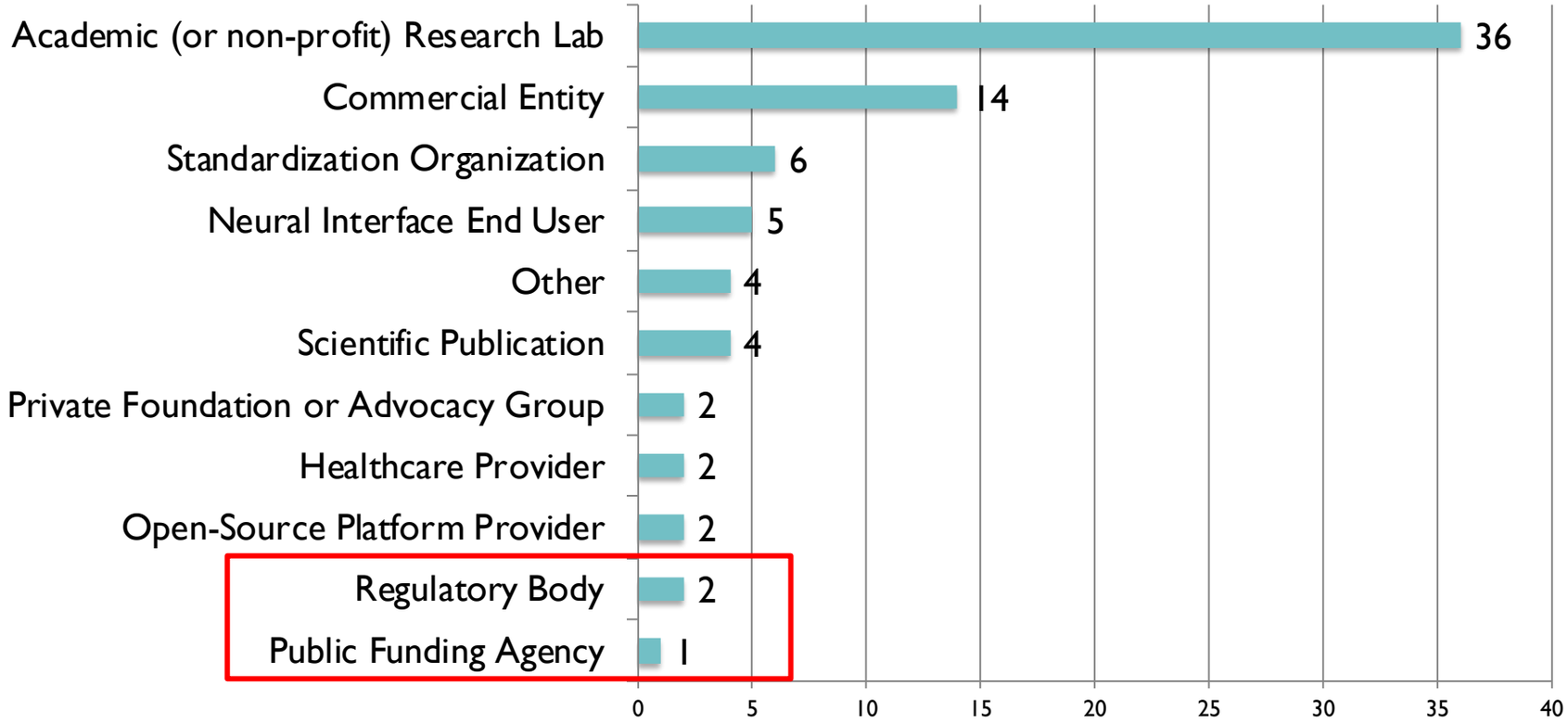
- **Sponsoring Society & Committee:** IEEE Engineering in Medicine & Biology Society/Standards Committee (EMB/Stds Com)
- **Outgrowth of IEEE Industry Connections Activity IC17-007: NeuroTechnologies for Brain-Machine Interfaces (NT-BMI)**
  - Scope of NT-BMI: provide summary & gap analysis of BMI landscape w. respect to standardization, as precursor for further BMI standardization
  - More Info: https://standards.ieee.org/industry-connections/neurotechnologies-for-brain-machine-interfacing.html
  - WG conception at BMI Standardization Workshop, BCI Society Meeting, May 24, 2018 -- Asilomar, CA (Chaired by NT-BMI Leadership)
- **Additional Active Working Groups** originating from NT-BMI
  - P2731 – Standard for Unified Terminology for Brain-Computer Interfaces
  - P2725.1 – Standard for Microwave Medical Imaging Device Safety

Working Group P2794 Composition

- **WG Roster: 53 Total Participants**
  - 37 Members (25 Voting, 12 Non-Voting)
  - 13 Observers + 3 IEEE Staff

- **Distribution of WG Participant Affiliations:**

(*participants may list more than one affiliation type*)



→ ***Seeking to increase neurotechnology stakeholder diversity!***

Working Group Objectives

AIMS OF STANDARDIZATION of neural interface research reporting:

1. **Primary (direct):** Improve the transparency, interpretability, reproducibility, and meta-analyzability of *in vivo* neural interface research (*human and animal*)

2. **Secondary (indirect):** Facilitate convergence towards rigorous standard experimental methodologies, outcome measures, and easily aggregated neural data representation structures (file formats, etc.)

3. **Tertiary (downstream):** Promote increased interoperability and clinical capability in the field of neurotechnology

[*Reference: IEEE Project Authorization Request (PAR) 2794, §5.4 – Purpose*]

Working Group Scope: *Reporting* Standard

Official Scope, defined by IEEE Project Authorization Request (PAR) 2794:

"*This Standard defines the essential characteristics and parameters of in vivo neural interface research studies (including clinical trials) to be reported in peer-reviewed scientific and clinical literature, including both minimum reporting standards and best-practice guidelines.*"

NOT Included in Scope *(… potential downstream effects…)*

- Specification of Neural Interface system design features, configurations, or performance parameters
- Explicit requirements on experimental methodology
- Use of specific neurodata file formats and data structures

WG P2794 – Scope of Standardization

→ **Challenge #1: How to Define "Neural Interface" (NIx), as addressed by our Standard?**

➢ not a currently recognized standard term **This expansive definition could be interpreted to include:**

- Brain-Computer Interfaces: EEG, ECoG, Intracortical Arrays
- Peripheral Nerve Interfaces: invasive, non-invasive
- Neuroimaging: fMRI, fNIRS, MEG, optogenetics
- Indirect Neural Modalities: electromyography (EMG), electrooculography (EOG), etc.
- *Neuromodulation*: DBS, spinal cord stimulation, peripheral nerve stimulation, focused ultrasound… FES??

WG P2794 – Group Organization (Strategy)

→ **Challenge #1: How to Define "Neural Interface" (NIx), as addressed by our Standard?**

- Fundamental Balance (Tension) between:

1. Want to create a standard with enough technological specificity to be useful to neurotech researchers & developers; AND
2. Want to create a Standard that serves as a framework enabling coherent communication between experts (engineers, researchers, clinicians, etc.) in different fields of expertise!

- *"Looking for a system to describe and manage complexity"*

WG P2794 – Scope of Standardization

Challenge #1: How to Define "Neural Interface" (NIx), as addressed by our Standard?

→ **Working Solution: distinguish between 2 (3) different domains of scope:**

1. The ***Physical Interface (Technological) Scope:*** the set of all technologies to which our Standard may apply
2. The ***Application Scope:*** The set of all (research) uses of NIx technology to which our Standard may applies
3. (TBD…) ***+: Epistemological (Informational) Scope:*** The set of all aspects of NIx research to which our Standard applies

WG P2794 – Scope of Standardization

Physical Interface (Technological) Scope – As defined thus far by WG:

- <u>Definitively Include:</u> "systems that record or modulate *biological signals directly in neural tissue*"
- <u>Potentially Include:</u> "systems that record or modulate *biological signals of neurological origin*" (including EMG, EOG, etc.)
- <u>Exclude:</u> systems measuring *motor output* (e.g. IMUs, eye tracking, MoCap) that don't directly measure *biosignals*

WG P2794 – Scope of Standardization

(Potential) Epistemological Scope *(to be refined…):*

- Experimental methodology and outcome measures
- Recording configurations and parameters
- Cognitive aspects & ontology
- Signal processing, neurodata feature extraction, and standard file formats
- Data analysis and statistical analysis methods
- Data aggregability and shareability
- Data security?
- NeuroEthics?

WG P2794 – Scope of Standardization

→ **QUESTION relating to Epistemological Scope:**

To what extent <u>can</u> and <u>should</u> the *reporting requirements and guidelines* established by our Standard be formulated to influence experimental methodology and NIx system design/performance themselves?

➢ ***DECISION: Our Standard will remain officially agnostic regarding experimental methods, choice of outcome/performance measures, NIx system design, and NIx configuration parameters.***

- …rather, we will simply specify the aspects of methodology and NIx system design/configuration that must be *reported* in 2794-compliant documents
- … prescriptive requirements will be left to the resulting scientific & neurotech community consensus, and the policy decisions of scientific publishers and device regulators.

WG P2794 – Scope of Standardization

→ Benefits of "Design & Methods-Agnostic" Policy:

1. NO CONSTRAINT on Innovation
2. Minimize barriers to adoption & adherence
3. Improved longevity of Standard: applicability (& extensibility) to new devices and methodologies not yet in existence
4. Accelerate discovery & innovation via improved quality of experiments, results, and information sharing
5. Accelerated commercial development (via regulatory approval) via rigorous, development-aligned research practices
    - Minimize project failures due to flawed study design or execution
    - Reduce barriers to translational research & commercial development

WG P2794 – Group Organization (Strategy)

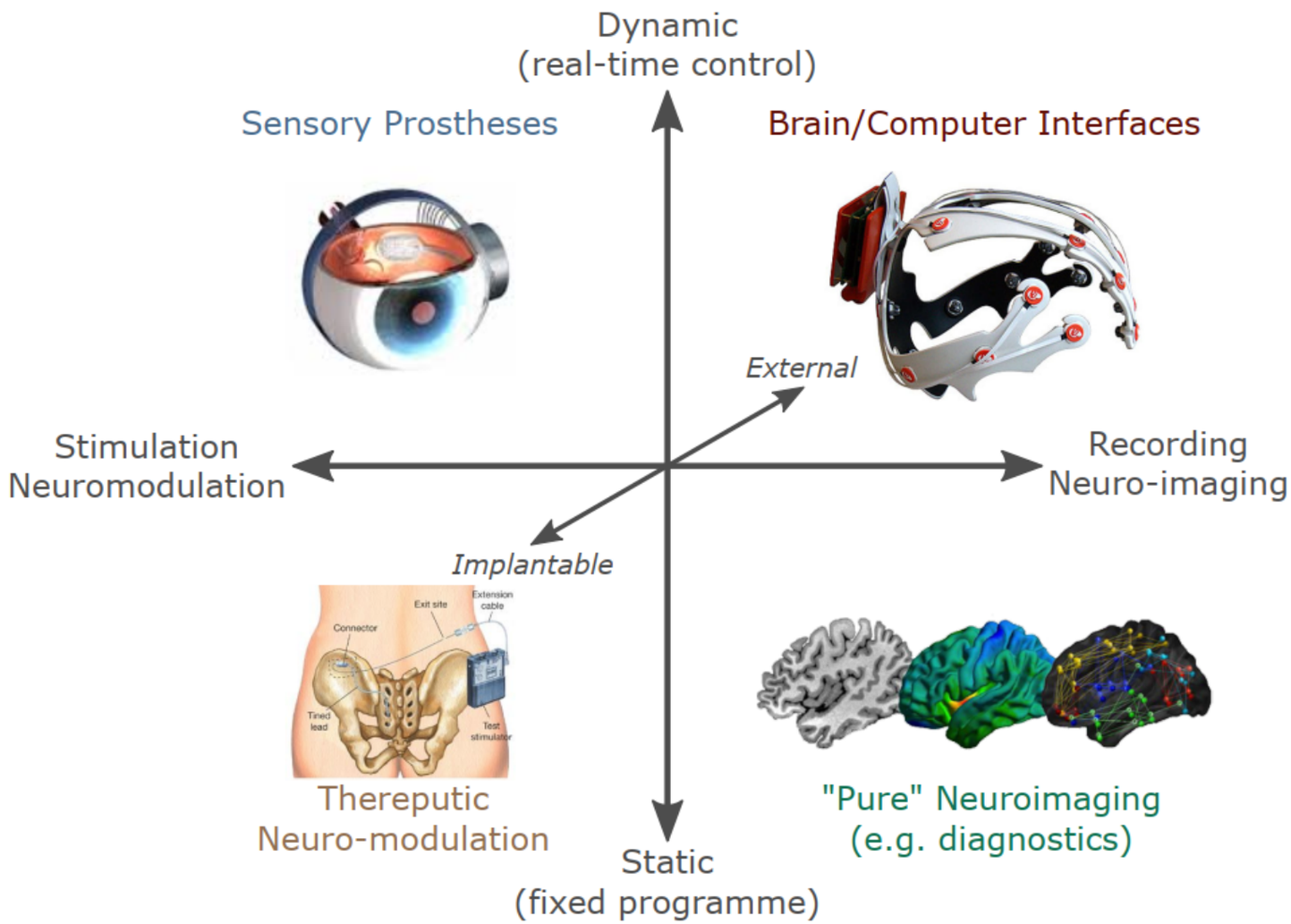
→ **Challenge #2: How to segment our WG into working sub-groups?**

- Sub-group segmentation would ideally (but not necessarily) reflect the organization of the final standard…

- **Vertical** (technology-based) **vs. Horizontal** (application or research aspect-based) **Hierarchy?**

WG Segmentation … via NIx taxonomy?

{ℕ𝕀} The set of all neural interfaces



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WG P2794 – Group Organization (Strategy)

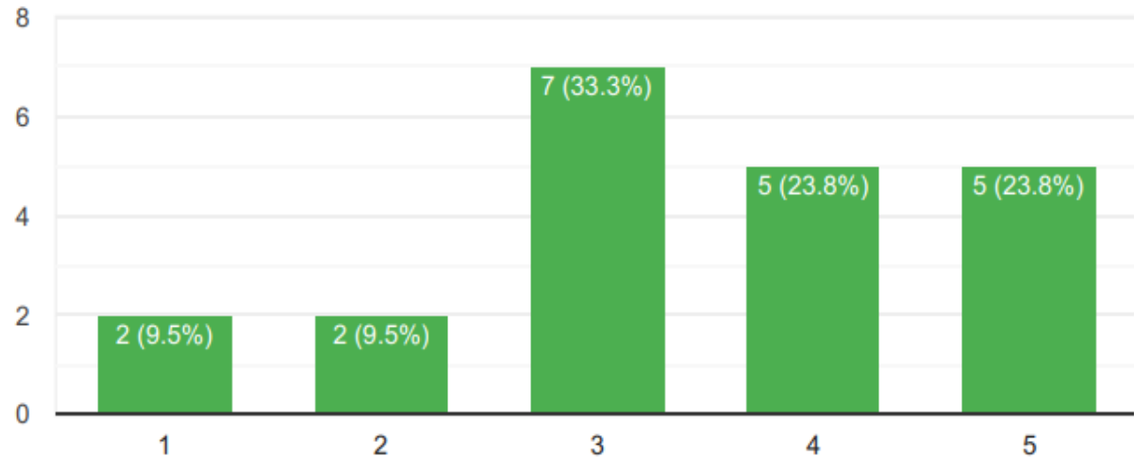
Challenge #2: How to segment our WG into working sub-groups? …

- **SOLUTION:** Segment WG based on distribution of member expertise

- WG Member expertise survey:

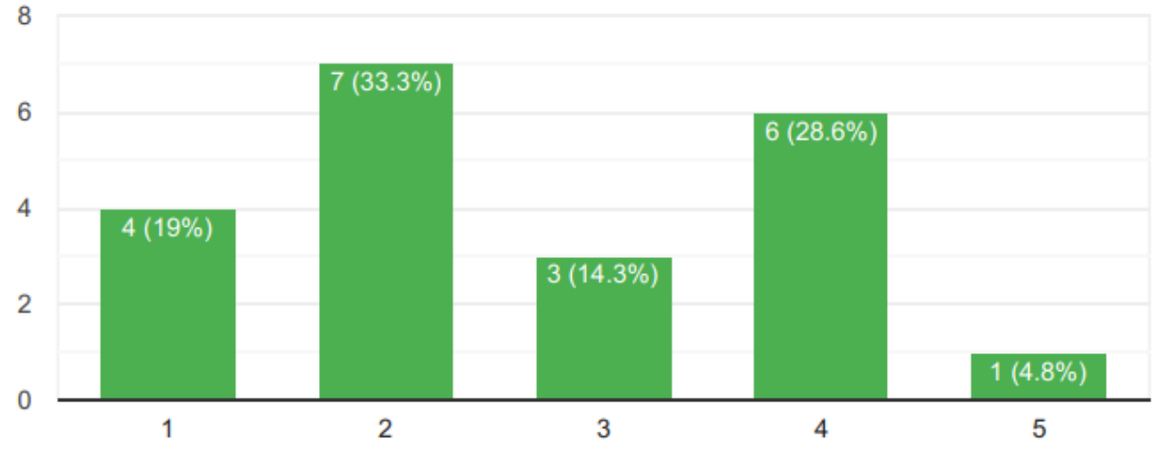
How technology (modality)-specific is your expertise?

21 responses



How broad is your subject area expertise?

21 responses



WG P2794 – Group Organization (Strategy)

Challenge #2: How to segment our WG into working sub-groups? …

- **SOLUTION:** Segment WG based on distribution of member expertise
  → **6 sub-groups total: 5 technology-oriented ("vertical") groups:**
    - EEGs for BCI
    - Invasive BCIs (intracortical, ECoG)
    - Peripheral Neural Interfaces
    - Neuroimaging
    - Neuromodulation

  … + **"Horizontal Integration" group**, to coordinate & harmonize others

- Tentative plan to develop Standard with a modular, layered architecture, that enables referencing of requirements in a 3 domains of scope (tech-based, application-based, research epistemology-based)

YOUR INPUT ENCOURAGED!! … *and Thank You*!

- **Via direct WG Participation**
  - ➢ Seeking to increase NeuroTech stakeholder diversity
    - Scientific Publishers
    - (Medical) Device Regulators
    - … + Clinicians? … End-Users?
- **By Sharing your Experience:** First-hand descriptions of use cases for our Std and testimonials of its potential value to you
  - ➢ How would the proposed Standard improve your NeuroTech research, development, or quality assurance capabilities?
  - ➢ How has the *lack* of standardization in this area presented a challenge or barrier to your past efforts?

Current & Future WG Activity

- **Physical Interface-Oriented ("Vertical") Groups**: Generate list of epistemological aspects to be reported, to make the Standard useful
- **Horizontal Integration Group**: Inventory and gap analysis of existing reporting standards, best-practice guidelines, and initiatives
  - **Clinical trial and meta-analysis reporting guidelines & initiatives** (CONSORT, FAIR, PRISMA, EQUATOR, etc.) re: NeuroTech specificity
  - **Neurodata-specific standardization initiatives**: Neurodata Without Borders, INCF, COBIDAS, Brain Imaging Data Structure (BIDS), NeuroImaging Data Model (NIDM)
  - **Standard data structures & file formats** – e.g. XDF, HDF5
  - **Open source platforms & tools for Neurotech interoperability** – e.g. OpenBCI, Lab Streaming Layer, BCI2000, OpenVIBE
  - **Other NeuroTech Stds Working Groups** – eg. IEEE P2731 (Unified BCI Terminology)
  - **Clinical Neurophysiology Data and Electronic Health Record formats?** – e.g. MEF3

➢ *… then develop our Standard to address the gaps!*

Current & Future WG Activity

- Upcoming WG-Related Events
  - RSNIR Workshop at IEEE Systems, Man, Cybernetics (SMC) Conference (Bari, Italy, Oct 6-9, 2019)
  - Next Teleconference: Wed, Sept 25 – 15:30-17:00 CET (9:30-11:00 EDT)

➢ ***To learn more, provide input, or participate***:

➢ RSNIR public web page: https://sagroups.ieee.org/2794/

➢ Direct Contact: z.mckinney@ieee.org; y.yuan@ieee.org