

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

IEEE Engineering in Medicine & Biology Conference (EMBC) 2019

Minisymposium on Global Standards Development for Biomedical Technologies

Session WeC21 - July 24, 2019, 14:00-15:30

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## Overview (Objectives)

- **WHY Standardize?**
  - Rationale for standardization of neural interface research reporting
- **WHAT to Standardize (first)?**
  - 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

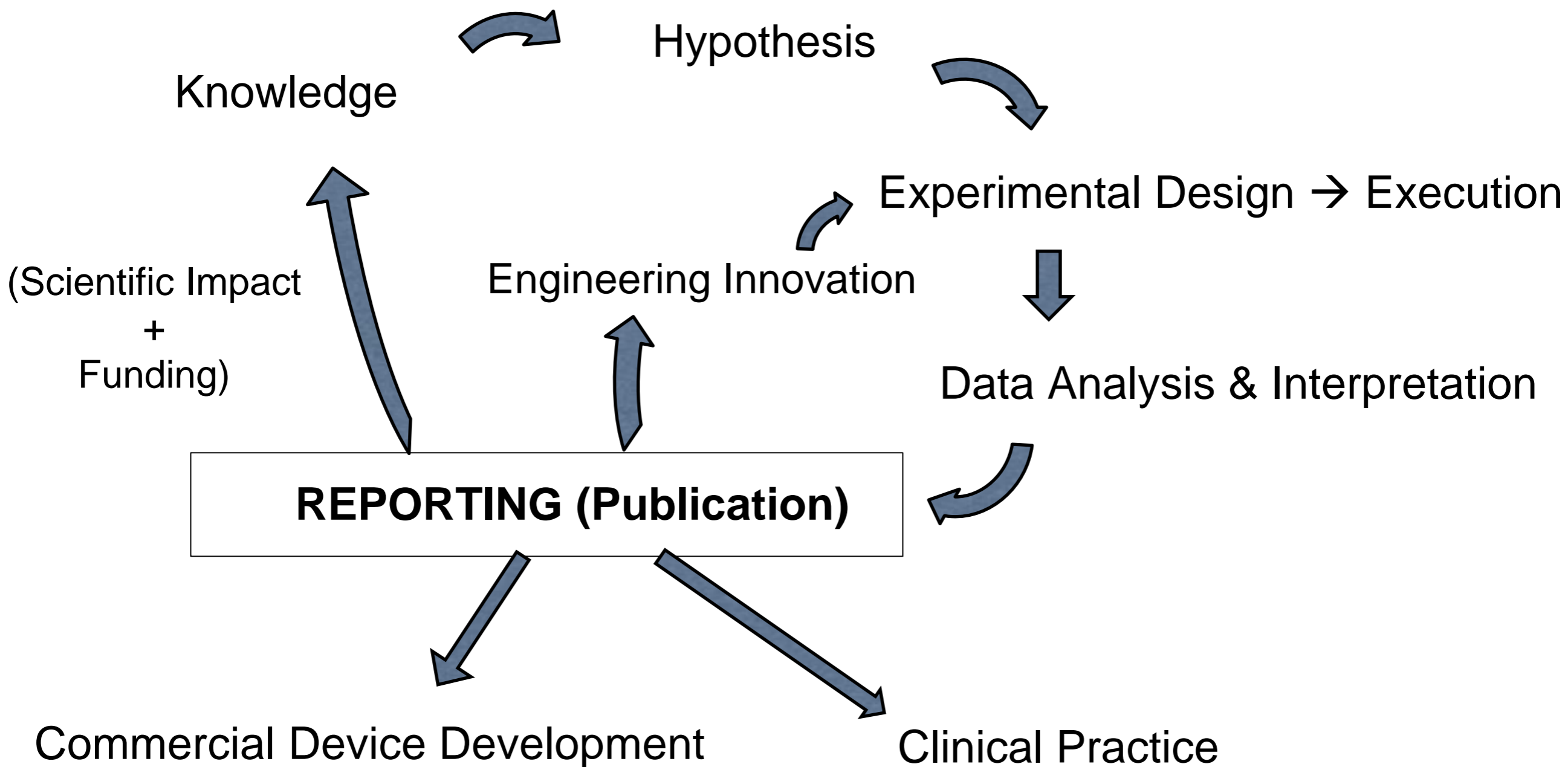
### 2. Assimilation (Information Integration)

- 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*?

- **Rigorous experimentation and reporting is the way to validate and communicate the *value of neurotechnology***
  - To scientific reviewers
  - To funding agencies
  - To (medical) device regulators
  - To healthcare payers
  - To device users (doctors, clinicians, patients)
  
- **High-quality, high-impact publications are a primary *de facto* objective for neurotechnology researchers**
  
- **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](mailto:z.mckinney@ieee.org))

- b. **Vice Chair:** Dennis McBride – NeuroRx, Source America

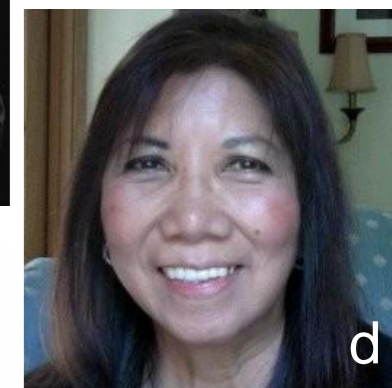
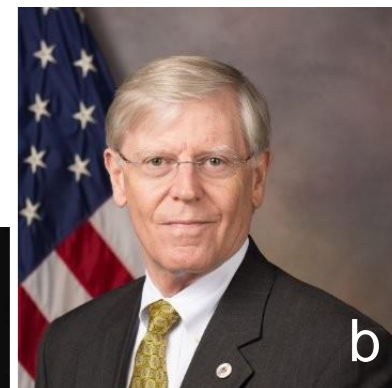
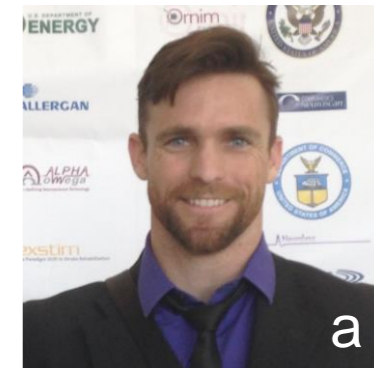
- c. **Secretary:** Yu Yuan – Senses Global Labs & Ventures

- **Sponsoring Committee Representative:**

- d. Carole Carey – C3-Carey Consultants, EMB/Stds Com

- **IEEE Support Staff**

- e. Tom Thompson

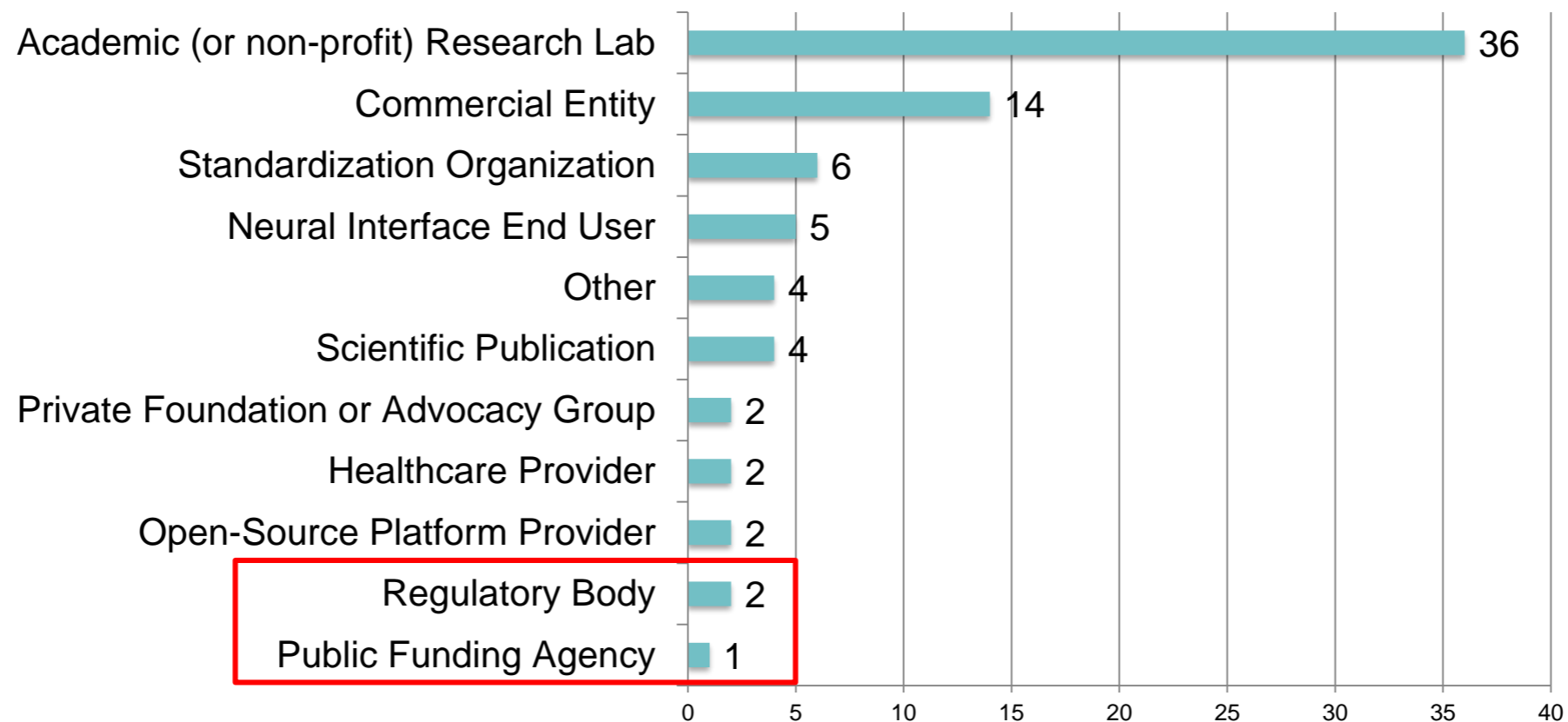


## WG P2794 Affiliation

- **Sponsoring Society & Committee:** IEEE Engineering in Medicine & Biology Society/Standards Committee (EMB/Std 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” (Nlx), 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 Nlx technology to which our Standard may applies
3. (TBD...) ***+: Epistemological (Informational) Scope***: The set of all aspects of Nlx research to which our Standard applies

## WG P2794 – Scope of Standardization

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

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

## WG P2794 – Scope of Standardization

### **(Potential) Epistemological Scope (TBD):**

- 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 security and shareability?
- NeuroEthics?

## WG P2794 – Scope of Standardization

### → **QUESTION** relating to **Epistemological Scope**:

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

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

- ...rather, we will simply specify the aspects of methodology and Nlx 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:

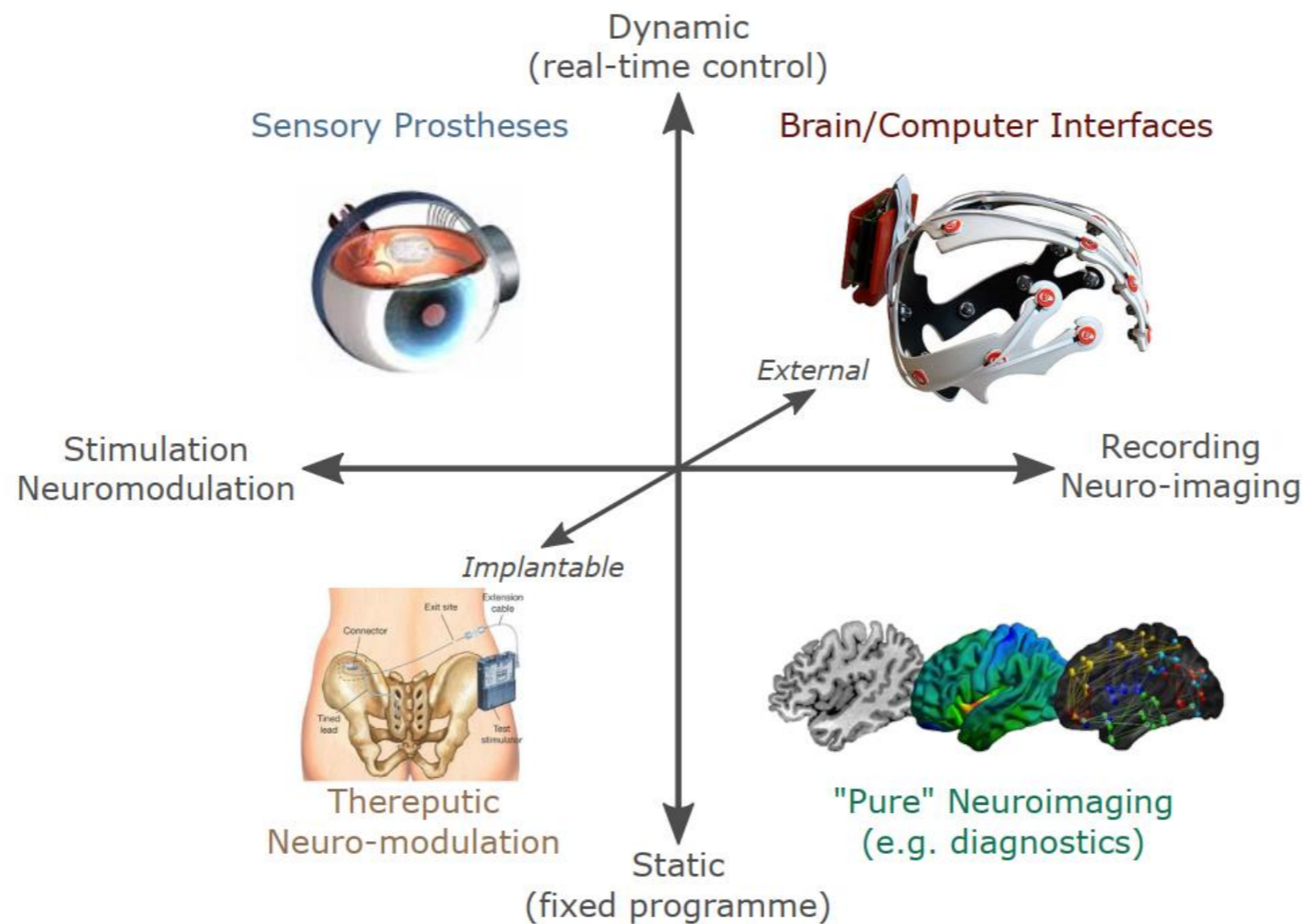
1. NO CONSTRAINT on Innovation
2. Minimize barriers to adoption & adherence
3. Improved longevity of Standard: applicability (& extensibility) to new devices and methodologies not yet in existence
4. Accelerate discovery & innovation via improved quality of experiments, results, and information sharing
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



## WG P2794 – Group Organization (Strategy)

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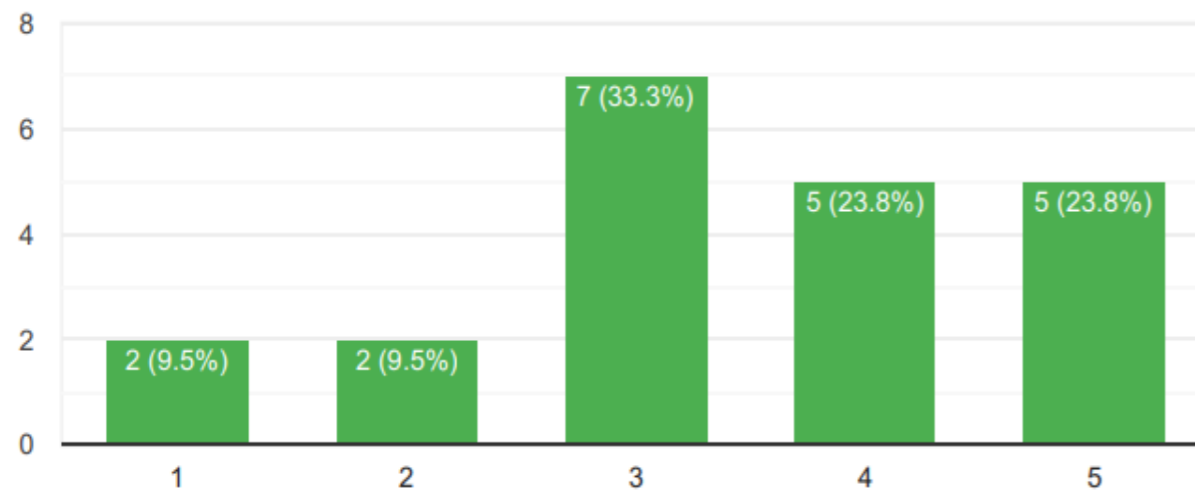
## WG P2794 – Group Organization (Strategy)

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

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

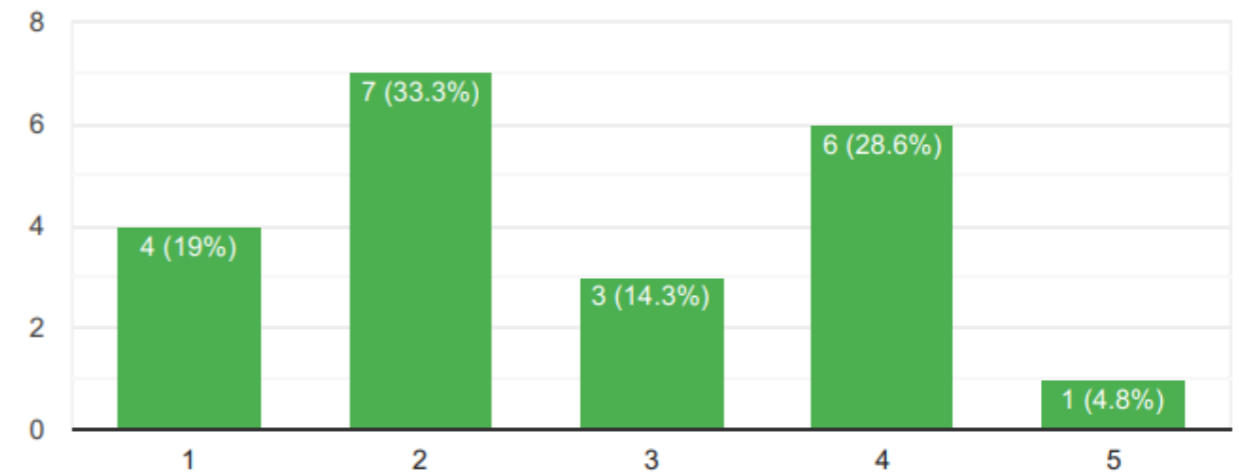
How technology (modality)-specific is your expertise?

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

- Current WG Action Items:
  - **Physical Interface-Oriented (“Vertical”) Groups:** Generate list of epistemological aspects to be reported, to make the Std useful
  - **Horizontal Integration Group:** Review & gap analysis of existing reporting guidelines & initiatives (CONSORT, FAIR, PRISMA, EQUATOR, etc.) for NeuroTech specificity
    - ... *then develop our Standard to address the gaps!*
- Upcoming WG-Related Events
  - NeuroTech Stds workshop at 2019 Graz BCI Conference (Sept 16-20)
  - RSNIR Workshop at IEEE Systems, Man, Cybernetics (SMC) Conference (Bari, Italy, Oct 6-9, 2019)