Neuro Technologies for Brain-Machine Interfacing

Industry Connections Activity Initiation Document (ICAID)

Version: 4.0, 5 April 2023

IC17-007-04 Approved by the CAG 10 July 2023

Instructions

- Instructions on how to fill out this form are shown in red. Please leave the instructions in the final document and simply add the requested information where indicated.
- Spell out each acronym the first time it is used. For example, "United Nations (UN)."
- Shaded Text indicates a placeholder that should be replaced with information specific to this ICAID, and the shading removed.
- Completed forms, in Word format, or any questions should be sent to the IEEE Standards Association (IEEE SA) Industry Connections Committee (ICCom) Administrator at the following address: industryconnections@ieee.org.
- The version number above, along with the date, may be used by the submitter to distinguish successive updates of this document. A separate, unique Industry Connections (IC) Activity Number will be assigned when the document is submitted to the ICCom Administrator.

1. Contact

Provide the name and contact information of the primary contact person for this IC activity. Affiliation is any entity that provides the person financial or other substantive support, for which the person may feel an obligation. If necessary, a second/alternate contact person's information may also be provided.

Name: Ricardo Chavarriaga (Chair)
Email Address: r_chavarriaga@ieee.org
Employer: Zurich University of Applied Sciences (ZHAW), Switzerland
Affiliation: Confederation of Laboratories for AI Research in Europe (CLAIRE)

Name: José Contreras-Vidal
Email Address: jlcontr2@Central.UH.EDU
Employer: University of Houston, USA
Affiliation: NSF IUCRC BRAIN Center

IEEE collects personal data on this form, which is made publicly available, to allow communication by materially interested parties and with Activity Oversight Committee and Activity officers who are responsible for IEEE work items.

2. Participation and Voting Model

Specify whether this activity will be entity-based (participants are entities, which may have multiple representatives, one-entity-one-vote), or individual-based (participants represent themselves, one-person-one-vote).

Individual-Based

3. Purpose

3.1 Motivation and Goal

Briefly explain the context and motivation for starting this IC activity, and the overall purpose or goal to be accomplished.

The field of Brain-Machine Interfacing (BMI) (also referred to as Brain Computer Interface, BCI) is experiencing a transformative with more and more organizations interested in capitalizing the promises of these technologies through product development. Consistent support from public and private organizations is expected to continue and some organizations predict the field to experience exponential growth.

In the previous years, this IC-activity has identified several gaps in the standardization of these technologies and has been key in the creation of three new IEEE Standardizations projects addressing novel neuroimaging technologies, reporting of experiments with neural interfaces and specification of BMI systems. The findings of the IC-activity have also been influential in other related initiatives. A fact that is reflected by the participation of its members in efforts such as the preparation of the "Organisation for the Economic Cooperation and Development" (OECD) recommendations for Responsible Innovation in Neurotechnology Enterprises, and the Working group on Data Sharing and Standards of the International Brain Initiative (IBI).

As it has been constantly pointed out in this activity, the lack of specific standards on neurotechnologies for BMI hinders the interoperability, and regulatory compliance of new devices and in consequence, constitutes a barrier for industrial applications to access a wide market. Moreover, the field of neurotechnologies is constantly evolving and development of standards should permanently follow this evolution. For this reason, we propose the renewal of this activity focusing on standardization areas that have been identified as key to the technology transfer process. Namely, the interoperability of the multiple modules that compose a BMI (including measuring and analysis of neural activity, and provision of feedback to the user through different means), and the coherent development of standards for both consumer and clinical BMI applications.

3.2 Related Work

Provide a brief comparison of this activity to existing, related efforts or standards of which you are aware (industry associations, consortia, standardization activities, etc.).

This IEEE IC-activity was one of the first initiatives directly focused on the study and development of voluntary consensus standards for BMI/BCI-related neurotechnology. Nonetheless, the awareness of the importance of this issue has been increasing thanks to efforts by this group and other stakeholders. Some relevant work includes:

- OECD Recommendation on Responsible Innovation in Neurotechnology, Dec 2019 (Link)
- US Food & Drug Administration (FDA) guidance "Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation - Non-clinical Testing and Clinical Considerations" (Link).
- International Brain Initiative Working Group: Data Sharing and Standards (Link)
- EU-funded projects EUROBENCH (Link) and INBOTS (Link). Although not related explicitly to neurotechnologies, these projects focus on benchmarking of robotics, which is one of the complementary technologies for BCI.
- International Neuroinformatics Coordinating Facility, (INCF) in a non-profit organization that promotes community-supported standards and good practices in neuroinformatics (Link)
- IEEE Brain Initiative and IEEE Neuroethics framework (Link)

3.3 Previously Published Material

Provide a list of any known previously published material intended for inclusion in the proposed deliverables of this activity.

Since its creation the IC-activity produced the following material that will serve as sources for future deliverables:

- IEEE SA Standards Roadmap : Neurotechnologies for Brain-Machine Interfacing (Link). This document, released in Feb 2020 is the main deliverable of the IC-activity so far.

- Chavarriaga, Ricardo, 2020. Standards for neurotechnologies and brain-machine interfacing. IEEE Systems, Man, and Cybernetics Magazine. 6(3), pp.50-51. doi:10.1109/MSMC.2020.2995438

- Paper series on Standards for BMI in the IEEE Open Journal of Engineering in Medicine and Biology, Feb 2021
  - R. Chavarriaga, C. Carey, J. L. Contreras-Vidal, Z. McKinney and L. Bianchi, "Standardization of Neurotechnology for Brain-Machine Interfacing: State of the Art and Recommendations," in IEEE Open Journal of Engineering in Medicine and Biology, vol. 2, pp. 71-73, 2021, doi: 10.1109/OJEMB.2021.3061328.
  - C. Easttom et al., "A Functional Model for Unifying Brain Computer Interface Terminology," in IEEE Open Journal of Engineering in Medicine and Biology, vol. 2, pp. 91-96, 2021, doi:

10.1109/OJEMB.2021.3057471.

- C. D. Eiber et al., "Preliminary Minimum Reporting Requirements for In-Vivo Neural Interface Research: I. Implantable Neural Interfaces," in IEEE Open Journal of Engineering in Medicine and Biology, vol. 2, pp. 74-83, 2021, doi: 10.1109/OJEMB.2021.3060919.
- A. Y. Paek et al., "A Roadmap Towards Standards for Neurally Controlled End Effectors," in IEEE Open Journal of Engineering in Medicine and Biology, vol. 2, pp. 84-90, 2021, doi: 10.1109/OJEMB.2021.3059161.

Other related material, not directly produced by the group. Note that several members of the IC-group were involved in the production of this material (See also Section 3.2):

- World Intellectual Property Organisation (WIPO) Report: Technology Trends in Assistive Technology, Mar 2021 (Link)
- IEEE Brain White paper : Future Neural Therapeutics, Version 2, Dec 2020 (Link)
- Y. Paek, J. A. Brantley, B. J. Evans and J. L. Contreras-Vidal, "Concerns in the Blurred Divisions Between Medical and Consumer Neurotechnology," in IEEE Systems Journal, Nov 2020 doi: 10.1109/JSYST.2020.3032609.
- OECD Recommendation on Responsible Innovation in Neurotechnology, Dec 2019 (Link)
- FDA guidance “Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation - Non-clinical Testing and Clinical Considerations”, Feb 2019 (Link).
- Huggins J. E., et al. (2022) Workshops of the eighth international brain–computer interface meeting: BCIs: the next frontier, Brain-Computer Interfaces, 9:2, 69-101, 2022. doi: 10.1080/2326263X.2021.2009654 (Link)
- Ienca et al. Towards a Governance Framework for Brain Data. Neuroethics 15(20), 2022 (Link)
- Eke, D., et al. International Data Governance for Neuroscience. Neuron, 110(4), 600–612, 2021. doi:10.1016/j.neuron.2021.11.017 (Link)
- “Neurotechnologies: The New Frontier for International Governance” GCSP Strategic Security Analyses. Apr 2023 (Link)

3.4 Potential Markets Served

Indicate the main beneficiaries of this work, and what the potential impact might be.

BMI-related technologies are expected to have increasing impact in multiple markets including:

- Clinical markets
  - Motor rehabilitation
  - Assistive technologies, including neuroprosthetics, exo-skeletons, and communication devices
  - Diagnosis and therapies for motor and cognitive disorders
  - Health monitoring, in particular for healthy aging
- Non-clinical markets
  - Cognitive training in industrial and military applications

- o Exoskeleton control in industrial and military applications
- o Gaming
- o Cognitive monitoring: well-being support, cognitive training, sleep monitoring
- o Internet of Things and Domotics

3.5 How will the activity benefit the IEEE, society, or humanity?

Describe how this activity will benefit the IEEE, society, or humanity.

BMI technologies can have a disruptive effect on how humans interact with intelligent machines. This potential brings great potential but also inherent risks. Given the link between the brain and the cognitive capabilities and mental personhood the possibility of measuring and modulating neural activity requires technology development to follow responsible practices. Continuous evaluation and development of consensus standards in a global platform will empower the community to develop technology-based products that are fit for purpose while limiting the risks. This promotes faster development of new solutions and higher adoption of neurotechnologies.

IEEE is a world leader in providing guidance to researchers, innovators and decision makers in ethically aligned design and robust technical standards. Renewal of this activity will help IEEE to continue being an important player in the international dialogue about emerging technologies both in the technical, organizational, and societal levels.

4. Estimated Timeframe

Indicate approximately how long you expect this activity to operate to achieve its proposed results (e.g., time to completion of all deliverables).

Expected Completion Date: 06/2025

IC activities are chartered for two years at a time. Activities are eligible for extension upon request and review by ICCom and the responsible committee of the IEEE SA Board of Governors. Should an extension be required, please notify the ICCom Administrator prior to the two-year mark.

5. Proposed Deliverables

Outline the anticipated deliverables and output from this IC activity, such as documents (e.g., white papers, reports), proposals for standards, conferences and workshops, databases, computer code, etc., and indicate the expected timeframe for each.

The deliverables for this IC activity will be in nature similar to the previous period:

1. Provide an updated overview of all standards activity that is specifically related to BMI-related neurotechnologies.
2. Report on gaps in the existing standards and a plan to address these gaps

Evaluate the use of digital platforms to provide the up-to-date information resulting from deliverables 1 and 2.
3. Organize or contribute to at least 5 special sessions and workshops on topics of improving BMI research and development through standards development and adoption.

These deliverables will provide an updated version of findings and recommendations included in the Standards Roadmap released in 2020 and organize special sessions and workshops focused on the process of developing new standards for BMI.

5.1 Open Source Software Development

Indicate whether this IC Activity will develop or incorporate open source software in the deliverables. All contributions of open source software for use in Industry Connections activities shall be accompanied by an approved IEEE Contributor License Agreement (CLA) appropriate for the open source license under which the Work Product will be made available. CLAs, once accepted, are irrevocable. Industry Connections Activities shall comply with the IEEE SA open source policies and procedures and use the IEEE SA open source platform for development of open source software. Information on IEEE SA Open can be found at https://saopen.ieee.org/.

Open source software will be considered in the event the use of digital tools for providing information on the standards landscape is decided by the group. The necessary steps for complying with the IEEE SA regulations of this respect will be undertaken.

6. Funding Requirements

Outline any contracted services or other expenses that are currently anticipated, beyond the basic support services provided to all IC activities. Indicate how those funds are expected to be obtained (e.g., through participant fees, sponsorships, government, or other grants, etc.). Activities needing substantial funding may require additional reviews and approvals beyond ICCom.

Additional funding may be requested, if need be, for supporting participation of group members in relevant events.

7. Management and Procedures

7.1 Activity Oversight Committee

Indicate whether an IEEE Standards Committee or Standards Development Working Group has agreed to oversee this activity and its procedures.

Has an IEEE Standards Committee or Standards Development Working Group agreed to oversee this activity? Yes

If yes, indicate the IEEE committee's name and its chair's contact information.

IEEE Committee Name: IEEE EMBS Standards Committee
Chair's Name: Carole Carey
Chair's Email Address: c.carey@ieee.org

Additional IEEE committee information, if any. Please indicate if you are including a letter of support from the IEEE Committee that will oversee this activity.

IEEE collects personal data on this form, which is made publicly available, to allow communication by materially interested parties and with Activity Oversight Committee and Activity officers who are responsible for IEEE work items.

7.2 Activity Management

If no Activity Oversight Committee has been identified in 7.1 above, indicate how this activity will manage itself on a day-to-day basis (e.g., executive committee, officers, etc.).

Briefly outline activity management structure.

7.3 Procedures

Indicate what documented procedures will be used to guide the operations of this activity; either (a) modified baseline *Industry Connections Activity Policies and Procedures* (entity, individual), (b) *Abridged Industry Connections Activity Policies and Procedures* (entity, individual), (c) Standards Committee policies and procedures accepted by the IEEE SA Standards Board, or (d) Working Group policies and procedures accepted by the Working Group's Standards Committee. If option (a) is chosen, then ICCom review and approval of the P&P is required. If option (c) or (d) is chosen, then ICCom approval of the use of the P&P is required.

EMBS standards working group procedures under the EMBS Standards Committee Sponsor procedures

8. Participants

8.1 Stakeholder Communities

Indicate the stakeholder communities (the types of companies or other entities, or the different groups of individuals) that are expected to be interested in this IC activity and will be invited to participate.

Companies working in neurotechnologies including, but not limited to neural acquisition systems (Neuroimaging, EEG, ECoG, and multiunit activity), electrostimulation at central (TMS, tDCS, tACS) and peripheral (FES) levels. Related technologies comprising virtual reality systems and gaming, haptic devices and rehabilitation robotics. Interested companies in healthcare and rehabilitation, gaming applications, and wellness, as well as regulatory and other government agencies (such as US FDA, NIH, NINDS) are strongly involved in these topics, and have shown their interest in the

development of standards. In the renewed activity, we will engage with other governmental bodies outside the US, and transnational organizations (fruitful connections with OECD and the UN Human Rights council have been established). In addition, we will also engage with other groups focused on ethical frameworks and standards, including the IEEE Brain Neuroethics Framework, INCF and the IBI Working Group on Data Sharing and Standards.

8.2 Expected Number of Participants

Indicate the approximate number of entities (if entity-based) or individuals (if individual-based) expected to be actively involved in this activity.

Approximately 100 individuals from research institutions, companies and regulatory agencies are expected to take part the activity.

8.3 Initial Participants

Provide a few of the entities or individuals that will be participating from the outset. It is recommended there be at least three initial participants for an entity-based activity, or five initial participants (each with a different affiliation) for an individual-based activity.

Use the following table for an individual-based activity:

Individual Name	Employer	Affiliation
Ajay Pillai	ECS Tech	
Akshay Sihatha Ravindran	UT Houston	
Aldo Faisal	Imperial College London	
Alexander Kamrud	USAF	
Anand Kumar Shaw	L& L Technologies	
Ander Ramos-Murguialday	TECNALIA	
Andrea Biasiucci	Confinis	
Andreas Forsland	Cognixion	
Andrew Paek	UT Houston	
anp322@drexel.edu	Drexel University	

Aureli Soria-Frisch	Starlab Barcelona SLU	
Banu Onaral	Drexel University	
Bjorn-Erik Erlandson	KTH	
Carole C. Carey	C3-Carey Consultants	
Chhavi Chawla	Honeywell	
Chris Ullrich	Cognixion	
Christoph Guger	G.tec	
Dandan Huang	Zhejiang Lab	
David Eguren	UT Houston	
Donnella Comeau	Mass General Brigham	
Eduardo Lopez Larraz	Bitbrain	
Emil Hewage	CBAS	
Emma Rahman	BIOS Health Ltd	
Eric Pohlmeyer	DARPA	
Esteban Pino	Universidad de Concepciv≥n	
Evan Frantz	USAF	
Frederic Andres	National Institute of Technology, Tokyo	
Gangadhar Garipelli	Mindmaze	
Griffin Milsap	Johns Hopkins	
Hailey Eustace	CBAS	

Hasan AL-Nashash	American University of Sharjah	
Hasan Ayaz	Drexel University	
Heather Dean	US Food & Drug Administration (FDA)	
Houde Dai	Chinese Academy of Sciences	
Ivan Volosyak	Hochschule Rhein-Waal	
Jacob Robinson	MOTIF	
Jesus Cruz-Garza	UT Houston	
Jiangbo Pu	Institute of Biomedical Engineering	
Joel Libove	Furaxa	
John Onyiego	ElinscoSystems	
John Shambroom	Shambroom Associates	
José Contreras Vidal	UT Houston	
Julia Slocomb	FDA	
Juliet Law	CBAS	
Justin Brantley	UT Houston	
Kecin Nathan	UT Houston	
Kevin Clark	Cures Within Reach and NSF ACCESS Champions Service	
Khrishna Sirohi	Indian Institute of Technology at New Delhi.	
Kunal Paralikar	Medtronic	

Laura Cabrera	Penn State University	
Laura Galindo	Meta	
Luigi Bianchi	Tor Vergata University	
Margaret Thompson	U Washington	
Mark Melnykowycz	IDUN Technologies	
Matther Fifer	Johns Hopkins University	
Mohan Venkataramana	Experteze	
Moritz Thielen	IDUN Technologies	
Narisa Chu	CWLAb International	
Nathan Bridges	USAF	
Nick Langhals	NIH	
Nita Farahany	Duke University	
Paul Petronelli	PALM Associates	
Pradeep Balachandran	Technical Consultant ICT	
Rachel Schneider	Georgetown University	
Rafiul Amin	UT Houston	
Rashed-Al Mahfuz	UT Houston	
Ricardo Chavarriaga	ZHAW - CLAIRE	
Robert McCombe	Information Commisioner's Office, UK	
Robert Nickl	Johns Hopkins University	

Roberto Barra-Chicote	Amazon	
SANDHYA KUMARI GOLLA	SIDDARTHA INSTITUTE OF SCIENCE AND TECHNOLOGY	
Sasitharan Balasubramaniam	Waterford Institute of Technology (WIT)	
Sho Nakagome	UT Houston	
Simeon Okechukwu Ajakwe	Kumoh National Institute of Technology	
SRICHETA PARUI	Indian Institute of Technology Kharagpur	
Stephanie Thacker	Meta	
Stephen Bush	GE	
Stephen Bush	GE Global Research	
Sugimura Roy	National Institute of Advanced Industrial Science and Technology	
Sumit Soman	Centre for Development of Advanced Computing	
Tim Ganguly	USAF	
Tim Mullen	Intheon	
Vikas Malhotra	WOPLLI Technologies	
Walid Sousou	Wearable Sensing	
Walt Besio	U Rhode Island	
Yingxu Wang	U Calgary	

Yongtien He	UT Houston	
Zach McKinney	US Food & Drug Administration (FDA)	

8.4 Activity Supporter/Partner

Indicate whether an IEEE committee (including IEEE Societies and Technical Councils), other than the Oversight Committee, has agreed to participate or support this activity. Support may include, but is not limited to, financial support, marketing support and other ways to help the Activity complete its deliverables.

Has an IEEE Committee, other than the Oversight Committee, agreed to support this activity? No

If yes, indicate the IEEE committee's name and its chair's contact information.

IEEE Committee Name: Committee Name
Chair's Name: Full Name
Chair's Email Address: who@where

Please indicate if you are including a letter of support from the IEEE Committee.