

Neuro technologies for Brain-Machine Interfacing Industry Connections Activity Initiation Document (ICAID) Version: 2.0, May 2019

IC17-007-02 Approved by the IEEE-SASB 11 June 2019

Instructions

- Instructions on how to fill out this form are shown in red. It is recommended to leave the instructions in the final document and simply add the requested information where indicated.
- **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

Email Address: ricardo.chavarriaga@epfl.ch

Phone: +41(21)6936968

Employer: Ecole Polytechnique Fédérale de Lausanne, EPFL

Affiliation: Entity Name(s)

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).

Specify: "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.

Interest in Brain-Machine Interfacing (BMI)/Brain Computer Interface (BCI) is consistently growing and state-of-the-art in research is currently being tested on its intended end-users. Translation from laboratory proof-of concepts to viable clinical and assistive solutions, as well as consumer applications entails a large set of challenges.

The possibility of deploying and commercializing BMI/BCI-based solutions requires researchers, manufacturers, and regulatory agencies to ensure these devices comply with well-defined criteria on their safety and effectiveness. Furthermore, BMI/BCI systems typically require integration of multiple sub-components comprising measuring and analysis of neural activity, and provision of feedback to the user through different means (including displays, virtual reality systems, haptic interfaces and exo-skeletons, among others).

The lack of specific standards on neurotechnologies for BMI/BCI hinders the interoperability, and regulatory compliance of new devices and in consequence, consists a barrier for industrial applications to access a wide market. This activity has identified some priority areas that require standardization and also a lack of familiarity with the standard development process.

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.).

As of today, there has not been specific consortia or associations directly focused on the development of official 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 include:

- Publication of the FDA draft guidance “Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation - Non-clinical Testing and Clinical Considerations” ([link](#)). FDA participants of this effort are part of our IC-activity
- 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
- IEEE Brain Initiative

3.3. Previously Published Material

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

List the previously published material, if any.

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:

- 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
- Virtual and augmented reality
- Training in industrial and military applications
- Gaming
- Cognitive training

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: March 2021

IC activities are chartered for two years at a time. Activities are eligible for extension upon request and review by ICCom and the IEEE-SA Standards Board. 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 are expected to:

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

Organize special sessions and workshops focused on the process of developing new standards for BMI.

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.

7. Management and Procedures

7.1. IEEE Sponsoring Committee

Indicate whether an IEEE sponsoring committee of some form (e.g., an IEEE Standards Sponsor) has agreed to oversee this activity and its procedures.

Has an IEEE sponsoring committee agreed to oversee this activity?: Yes

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

Sponsoring Committee Name: IEEE EMBS Standards Committee

Chair's Name: Carole Carey

Chair's Email Address: carolecarey@mac.com

Chair's Phone: 301-776-9882

7.2. Activity Management

If no IEEE sponsoring 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).

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*, (b) Sponsor policies and procedures accepted by the IEEE-SA Standards Board, or (c) Working Group policies and procedures accepted by the Working Group's Sponsor. If option (a) is chosen, then ICCOM review and approval of the P&P is required. If option (b) or (c) 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 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 agencies (NIH, NINDS) are strongly involved in these topics, and have shown their interest in the development of 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 join the activity.

8.3. **Initial Participants**

Provide a list 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 entity-based activity:

| Entity | Primary Contact | Additional Representatives |
|-------------|---|--|
| Entity Name | Contact Name Email Address Phone Number | Name, Email Address Name, Email Address |
| | | |

Use the following table for an individual-based activity:

| Individual | Contact information | Company | email |
|--------------------------|---------------------|-----------------------------------|-------|
| Akshay Sujatha Ravindran | | University of Houston | |
| Ander Ramos-Murguialday | | TECNALIA | |
| Andrea Biasiucci | | confinis AG | |
| Andreas Forsland | | Cognixion | |
| Andrew Paek | | University of Houston | |
| ASHHAR KARALIKKADAN | | NTU SINGAPORE | |
| Aureli Soria-Frisch | | Starlab Barcelona SLU | |
| Banu Onaral | | Drexel University | |
| Bjorn-Erik Erlandson | | KTH/Royal Institute of Technology | |
| Carole Carey | | C3-Carey Consultants | |
| Christina Boyce | | IEEE-SA | |
| Christoph Guger | | g.tec medical engineering GmbH | |
| Christy Bahn | | IEEE Standards Association | |
| Colleen Lee | | FDA | |
| David Eguren | | University of Houston | |
| David McMullen | | NIH | |
| David Ojeda | | Mensia Technologies | |

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|--------------------------|--|---|--|
| Debra Best | | IEEE | |
| Devjani Saha | | FDA | |
| Dilranjan Wickramasuriya | | University of Houston | |
| Doug Gischlar | | IEEE | |
| Eduardo López-Larraz | | University of Tübingen | |
| Emil Hewage | | CBAS | |
| Emma Rahman | | BIOS | |
| Esteban Pino | | Universidad de Concepción | |
| Gangadhar Garipelli | | MindMaze SA | |
| Gregory Marchini | | IEEE | |
| Hailey Eustace | | Cambridge Bio-Augmentation Systems | |
| Hasan AL-Nashash | | American University of Sharjah | |
| Hasan Ayaz | | Drexel University | |
| Heather Dean | | FDA | |
| Houde Dai | | Haixi Institutes | |
| Ivan Volosyak | | Rhine-Waal University of Applied Sciences | |
| Jesus Cruz-Garza | | University of Houston | |
| Jiajun Chang | | University of Houston | |
| Joan Woolery | | IEEE-SA | |
| Joel Libove | | Furaxa | |
| John Shambroom | | Shambroom Associates | |
| Jose Contreras-Vidal | | University of Houston | |
| Joshua Gay | | IEEE-SA | |
| Jozef Legény | | Mensia Technologies | |
| Justin Brantley | | University of Houston | |
| Kelliann Wachrathit | | FDA | |
| Kevin Jose Acuña | | Pontifical Catholic University of Peru | |
| Kevin Nathan | | University of Houston | |
| Kunal Paralikar | | Medtronic | |
| Lizbeth Peralta-Malváez | | UDLAP | |
| Louis Mayaud | | Mensia Technologies | |
| Luigi Bianchi | | Tor Vergata University | |
| Luigi Napoli | | IEEE | |
| Marie PRAT | | Mensia Technologies | |
| Matthew Ceglia | | IEEE | |
| Matthew Fifer | | APL | |
| Matt Raymond | | NIH | |
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| Md Rashed-Al-Mahfuz | | University of Houston | |
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| Michael Kipness | | IEEE-SA | |
| Michael Smith | | IEEE SMC | |
| Munir Mohammed | | IEEE | |
| Narisa Nan Chu | | IEEE | |
| Nicholas Langhals | | NIH | |

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|----------------------|--|--|--|
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| Sinkuen Hawkins | | IEEE | |
| Stephen Bush | | GE | |
| Stuart Mason Dambrot | | | |
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| Zach McKinney | | Scuola Superiore Sant'Anna | |