

Topic idea submitted to IHI - Reference Number: TI_001198

Are you submitting the idea:

- in your personal capacity?
 on behalf of an organisation?

Please indicate the name of the group organisation: European Neurotechnology Consortium

Please select from the list below the type of stakeholders your organization represents:

Research/higher or secondary education organisation (private or public)

1 Title of your idea

Please provide a short title that accurately reflects the objective(s) of your idea:

Neuroelectronic medicine and the European health strategy

2 Scope

Explain the specific challenges/problems to be addressed by your idea and how these affect relevant stakeholders, taking into account what is already known and/or available in the field:

Neurological disorders affect millions of people with a devastating impact on what makes us human. One in three people in Europe suffer from neurological or psychiatric disorders. Until now, pharmaceuticals have been the major tool to treat nervous system diseases. However, many disorders lack effective pharmaceutical therapy. The proposal for an IHI topic addresses the emerging revolution in neuroelectronic medicine, transforming the way we treat disorders of the nervous system.

Neuroelectronic technologies form a direct link with the brain and have relatively few side-effects. They enable personalized therapy that adapts to the patient's symptoms and responsiveness of the tissue and have a high degree of reversibility compared to surgical methods such as resection. New methods to record and/or stimulate the tissue include high-density electrodes, optogenetics and ultrasound to record from and stimulate nerve cells. The proposal embarks on coordinated technological developments, to improve wireless data and power transfer enabling the operation of high resolution and high precision devices; methods to package technology in the body, to ensure the longevity of devices and to avoid unwanted tissue responses; developments in the area of micro-electrode technologies, allowing for the implantation of 100s to multiple 1000s of electrodes in a small volume of brain tissue; better understanding of the responses of the neural tissue and the immune system, developments of new forms of actuation, such as magnetoelectric nanoparticles, photobiomodulation, optogenetics and ultrasound, and further development and clinical translation of closed-loop control technologies based on an analysis of the societal and ethical impact.

Please indicate which IHI specific objective(s) (SO), as described in the IHI Strategic Research and Innovation Agenda (SRIA), your idea addresses:

["SO1: contribute towards a better understanding of the determinants of health and priority disease areas"]

"SO2: integrate fragmented health research and innovation efforts bringing together health industry sectors and other stakeholders, focusing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users"

"SO3: demonstrate the feasibility of people-centered, integrate health care solutions"]

Please select the keywords that are most relevant to your idea:

["Neurodegenerative diseases"]

"Mental health"

"Diagnosis"

"Interception"

"Treatment"

"Disease management"

"Digital health"

"Health technology"]

In alignment with the IHI specific objective(s) selected above, specify the objectives of your idea:

Neuroelectronic medicine capitalizes on advances in electronics, biomechanics, chemistry, physics, nanotechnologies, powerful computation and digital tools coupled with advances in brain science, medicine and opportunities in the brain health ecosystem. The proposal will bring these fields together to create new technologies to repair, restore and replace lost or impaired function of the nervous system. A unique strength of it is that the same technology base can be used to target multiple disease areas and brain regions and permits patient-specific and adaptive treatment.

We will build the European Neuroelectronic Medicine Platform (ENMP) to accelerate new scientific fields and commercial medical applications, prioritizing the development of novel neuroelectronic medicine and early feasibility studies. The platform technologies of ENMP will be thoroughly tested for safety, clinical operability, and efficacy so that new use cases have a regulatory advantage. We involve patients, their communities and clinicians from project design through to implementation, to enhance translation and market introduction and to address social, ethical and philosophical questions.

3 Expected impacts to be achieved by your idea

Briefly describe the expected impacts to be achieved by your idea, ensuring that they contribute to IHI general and relevant specific objectives, as described in the IHI SRIA:

Impacts are wider long-term effects on society (including the environment), the economy and science, enabled by the outcomes of R&I investments. Impacts generally occur sometime after the end of the project, e.g. successful implementation of digital solutions supporting people-centred care.

***IHI general objectives:** 1. contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations; 2. foster the development of safe, effective, people-centred and cost-effective innovations that respond to strategic unmet public health needs, by exhibiting, in at least 5 examples, the feasibility of integrating health care products or services, with demonstrated suitability for uptake by health care systems. The related projects should address the prevention, diagnosis, treatment and/or management of diseases affecting the EU population, including contribution to 'Europe's Beating Cancer Plan'; 3. drive cross-sectoral health innovation for a globally competitive European health industry and contribute to reaching the objectives of the new Industrial Strategy for Europe and the Pharmaceutical Strategy for Europe.*

Neurological and psychiatric diseases are the leading cause of disability with stroke, dementia and neurodegenerative disorders as drivers. In 2017, the total number of disability-adjusted life years attributable to neurological disorders was 21 million in the EU. The new technologies go beyond the existing neurotechnological solutions such as deep-brain-stimulation and cochlear implants. However, the US with a 53.6% share of the total number of companies is ahead of Europe with 20.3%. The market volume is growing quickly, so that investments can have a large multiplier effect. Europe can catch up provided we enhance the ecosystem joining researchers, medical doctors and companies to expand the possibilities of linking digital technology to the nervous system. Return of investment can occur via applications of the same technical solutions to multiple diseases, lowering risk and increasing the potential gain.

4 Why should your idea become an IHI call topic?

Explain why collaboration through a cross-sectoral and multidisciplinary public private partnership is needed in particular:

Why does it require collaboration among several industry sectors (e.g. pharma, vaccines, biotech, medical devices, in vitro diagnostics, radiotherapy, medical imaging health ICT)?

Why does it require collaboration between private (industry) and public partners (e.g. academia, healthcare practitioners, patients, regulators)?

Cross-sectoral collaboration is needed to create the Neurotechnology Medicine Platform, because the potential of the modern microelectronics industry needs to be geared towards specific needs by the deep domain knowledge from fundamental and clinical neuroscience, combined with ICT and AI expertise, while taking into account the clinical trial design and management. Academic labs have the domain expertise, but they lack the scale, structure and technology access available in industry. Regulatory support is also needed to ensure safe and effective rollout of medical devices. Finally, the field of neuroelectronic medicine needs to address ethical, societal and philosophical questions concerning the impact of neurotechnology on an individual's identity, personality and privacy. These questions need to be addressed by ethicists, philosophers and neuroscientists, working with patients, their communities, clinicians, ICT technologists and different interest groups. As an integral part of the neuroelectronic medicine approach, rehabilitation programs will need to be developed, validated and provided to ensure training of the user.

Why is the contribution of industry needed to achieve the expected impacts?

***Contribution of industry:** Large companies that are members of the IHI industry partners (i.e. COCIR, EFPIA, EuropaBio, MedTech Europe, Vaccines Europe) contribute to the programme, primarily through 'in-kind' contributions (e.g. their researchers' time, laboratories, data, compounds). At least 45% of each project's total costs have to be in-kind contribution.*

Contribution of industry is needed because neurotechnology is an emerging market with a substantial potential where developments could only be scaled up through industry involvement. Industry is also the essential partner to implement the concept of modular engineering as part of the platform and to enable the substantial investments associated with the introduction of Class III medical devices. The industry's involvement is also essential to set up a manufacturing platform that can first provide components in lower volumes and disseminate them to leading European neuro-translational groups. The regulatory pathways will benefit from a platform of compatible modules – brain chips, implant materials, interfacing and encapsulation technologies, etc. – that can be used in various combinations for different targets in the nervous system and applications. The standardization of modules and interfaces and the sharing of data and protocols warrants that each new application may leverage the success of previous use cases, thereby maximising the return on the initial investment.