# *Topic idea submitted to IHI - Reference Number:* TI_001211

**Are you submitting the idea:**
☒ **in your personal capacity?**
☐ **on behalf of an organisation?**

## 1 Title of your idea

**Please provide a short title that accurately reflects the objective(s) of your idea**:
Creation of an artificial intelligence-powered data platform to support the development of diagnostics and precision medicine for myalgic encephalomyelitis/ chronic fatigue syndrome (ME/CFS) and long COVID

## 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:**
Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) is a debilitating, chronic, multisystem disease, which affects 0.2-0.3% of the population. Symptoms include severe and disabling physical and mental fatigue linked to post-exertional malaise, which does not improve with rest and seriously interferes with work activity and daily life tasks. It is estimated that 25% of patients are unable to leave the house or are bedbound, and more than 60% are unable to work. This poses a big socio-economic problem.
Pathogenesis and etiology of ME/CFS are not well understood. It can develop as a postviral (e.g., Epstein Barr virus, SARS-CoV2) disease, but in many instances the origin is unclear. Its manifestations include immunologic dysregulation, oxidative stress, defects of mitochondrial energy production and of the autonomic nervous system. No diagnostic tests or biomarkers have been established and no effective drugs are available for its treatment. Therapies are based on off-label drug use and a trial-and error approach. Side effects of ineffective drugs can permanently worsen the disease.
The proposed project hopes to generate an AI-powered data platform to include all information and results available from basic and clinical research, as well as patient experience. This should offer clinicians a holistic view of each patient and help decide which diagnostic tests to perform to better understand the disease process and subsequently predict how the patient will respond to different treatments.
The ultimate goal is to transform this currently untreatable, debilitating disease into a manageable one with minimal impact on quality of life and ability to work.

**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, treat- ment and management of diseases, meeting the needs of end-users "
"SO3: demonstrate the feasibility of people-centered, integrate health care solutions"
"SO4: exploit the full potential of digitalisation and date exchange in heath care"
"SO5: enable the development of new and improved evaluation methodologies and models for a comprehensive assessment of the added value of innovative and integrated health care solutions"]

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

["Non-communicable diseases"
"Immune system diseases"
"Metabolic diseases"
"Neurodegenerative diseases"
"Prediction"
"Detection"
"Diagnosis"
"Treatment"
"Disease management"]

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

Understanding the complex disease of ME/CFS at the physiological and molecular levels will provide measurable laboratory parameters for diagnosis and lead to patient characterization and stratification, as well as the development of monitoring devices.

Since ME/CFS currently is an incurable and debilitating disease with a disease onset mostly before the age of 40 and a prevalence of 0.2 – 0.3%, identifying effective therapies and/or cures is of utmost importance. This can only be achieved by bringing together all stakeholders, including patients, caregivers, basic research, medical device and pharma companies.

Biobank samples and studies to characterize patients at genetic, physiological and molecular levels have to be shared within the confines of the GDPR to build an AI tool comprising all available information. This should integrate data from preclinical and clinical research, pharmaceutical and diagnostics companies, as well as real-world data from patients, including readouts from wearable devices.

# 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.*

The project aims at a better understanding of ME/CFS leading to correct and early diagnosis. Active involvement of all stakeholders should enable the development of therapies, which are safe and effective and can be approved by the health authorities. The final goal is to provide precision medicine to patients with a currently very high unmet medical need. This requires the cooperation of patients and their caregivers with the medical community, basic research, medical technology- and pharmaceutical companies. In addition, digitalized data repositories and artificial intelligence are required to also take into account all the patient co-morbidities and respective treatments. Not only ME/CFS-, but also long COVID patients will benefit from the results. This way, they will gain access to innovations that meet their needs and cost-effective innovative solutions developed by industry can translate to a positive effect on their R&I investments.

# 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)?**

The development of adequate medical treatment for the complex disease ME/CFS is in its infancy. Reliable diagnostic tools are missing and there are no approved drugs. Since knowledge about ME/CFS is not yet common in the medical community, patients and their caregivers are a valuable source of information about the disease manifestations and impact of daily activities, nutrition, food supplements and drugs. Academic research has led to the elucidation of different mechanisms which are involved in limited sets of patients. It is therefore necessary to combine the present knowledge of public partners, e.g., healthcare professionals, patients and academia with the capabilities of medical device companies for the development of diagnostic tests and pharma companies for the discovery and development of therapies in order to stabilize, improve and eventually cure the disease.

**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.*

Currently there are neither diagnostic assays nor registered drugs for ME/CFS. Diagnosis is based on phenomenological criteria, and drug treatments rely on trial and error.
To characterize ME/CFS and long COVID with CFS manifestations and differentiate them from other

diseases with partially overlapping symptoms, different approaches have been used, including cellular assays, determination of proteins and metabolites in blood or urine, Raman spectroscopy and PET imaging. However, a straightforward, universally applicable test has not yet been developed. This will be the domain of diagnostics companies.
Pharma companies will contribute either with drugs already on the market or in development. These may address molecular mechanisms which will be found to be crucial for the disease process. Alternatively, when new targets are identified, only pharma partners are capable of making the investment to develop new drugs.