**Topic 1: An innovative decision-support system for improved care pathways for patients with neurodegenerative diseases and comorbidities**

All information regarding future IHI Call topics is indicative and subject to change. Final information about future IHI Calls will be communicated after approval by the IHI Governing Board.

**Expected impacts to be achieved by this topic**

The following impacts are expected:

- Enhanced cross-sectoral collaboration between healthcare industries, academia, and all relevant actors of the healthcare ecosystem (including patients and their organisations, carers, regulators, health care professionals/providers) enabling exchange of resources beyond data (such as analytical tools, material for training and professional development of personnel).

- Earlier and more precise diagnosis, more clinically effective interventions, better patient adherence, and reduced hospitalisation (reduction in re-admission/period of hospitalisation).

- Patient stratification based on clinical outcomes to support more patient-adapted interventions/therapeutics including potential emerging disease modifying therapies.

- Better patient clinical outcomes and improved patient experience for patients with neurodegenerative diseases.

- More cost-effective and better prepared care pathway management for patients with neurodegenerative diseases.

- Contribute to the ‘European Health Data Space’ by promoting better exchange and access to different types of health data and data generated by health technologies for the benefit of European citizens, health researchers and health policy makers.

**Expected outcomes**

R&I actions to be supported under this topic shall contribute to the following outcomes:

- A (sustainable) re-usable, interoperable, easily adaptable, and scalable digital platform, capable of translating a heterogeneous and fragmented set of complex measurable and analysable health data elements into a clinical-decision-support system that can guide patients to better health and quality of life. Initially designed for patients with neurodegenerative diseases and comorbidities, the platform's easy adaptability ensures its re-use in other health areas for the benefit of healthcare professionals, patients, families, and carers, thereby promoting its wider use.
• A sustainable framework for collaboration across specialities and all relevant stakeholders to foster social innovation to decrease the burden on patients, families, and carers and to develop models to incentivise/maintain collaboration and ensure feasibility of future implementation.

• Effective and agreed standards and guidelines that support both data collection and all operational features of the digital platform enabling health technology developers to create efficient clinical decision support systems for a more patient-centric and optimised delivery of healthcare interventions. Healthcare professionals/providers use these solutions leading to improvements in the healthcare pathways.

• Enhanced, and more reliable tools and methods (e.g., analytical tools and algorithms) able to provide (near) real time feedback on health interventions, including on the usability, efficacy/effectiveness, and the long-term safety of health technologies. Together, these enable healthcare professionals and providers to make more inclusive and efficient patient-centred decisions that, additionally, can aid the development of predictive simulation tools and models.

• Enhanced clinical interpretation of multi-modal, multi-parametric data, including socio-economical, which influence variations in the status of the patient with neurodegenerative disease and the required levels of care. This will be benefitting the patients, as a more person-centric treatment and care, and the healthcare providers as optimised allocation of resources, and prediction of how patients’ needs will change due to their co-morbid condition or other precipitating medical factors.

Scope

Neurodegenerative disorders represent a high societal burden impacting patients, their families, and the public health care systems. Patients with a neurodegenerative disorder frequently display at least one comorbidity, which together with the observed polypharmacy creates a highly complex system that needs better understanding to optimise current care pathways. While recent developments create cautious optimism that a disease-modifying therapy is on the horizon, the high disease prevalence and complex evaluation process when such a therapy becomes available, will create challenges for the already over-burdened healthcare system. This will increase the demand and importance of diagnostic and digital solutions to drive the related clinical pathways and optimize and personalize care delivery.

The primary objective of this topic is to develop a clinical decision-support system to enhance medical decisions with targeted clinical knowledge, patient information, and other health information for a more holistic approach to managing and treating patients with a neurodegenerative disease and a comorbid condition, addressing the needs of today, while creating preparedness for a future paradigm-shift in treatment.

Proposals should address a patient population with a neurodegenerative disease where there is evidence on the importance of comorbidities in their healthcare pathways and on patient quality of life. The choice of the comorbidity should consider the burden to the patients, the carers and the families and the availability of medical technology-generated data. Cancer is out of scope.

Applicants should develop a (sustainable) re-usable, interoperable, and scalable digital platform, to, safely and efficiently, collect, curate, store, share, access, integrate and analyse multimodal longitudinal, dynamic health data generated within and outside the healthcare setting,
This will require breaking existing data silos across different medical specialities to allow the dynamic flow of information on the concomitant conditions and their interplay to improve selection of the best possible care pathways, and patient adherence.

Data may include medical/laboratory data, automatically collected data, omics data, medical device data, treatment modality/intervention-type data, real-world evidence, including medical condition and lifestyle-related data collected via e-health solutions, smart devices, wearables, medical grade sensors and other patient self-reported data. Data on contextual information (setting and organization of care, staffing, payment models) should be considered, as well as data from patient registries. The patient perspective and notably their quality of life, will need to be sufficiently considered including via patient-reported experiences and outcomes measurements (PREMs; PROMs). The perspective of families and carers should be also included.

Applicants should consider leveraging relevant large datasets that are already available at national and/or European level.

Ensuring data quality will be of paramount importance. In addition, applicants should ensure trustworthy and safe sharing of patient data through ‘privacy and security by design’, as well as ample consideration for the control of data reuse by patients and health care professionals, for example by the implementation of ‘FAIR’ (findable, accessible, interoperable, and re-usable) data principles and a suitable data governance.

The platform should build upon suitable existing platforms or elements thereof (e.g. specialised research infrastructures, and/or developed by IMI projects) with proven efficiency and interoperability, complying with European privacy and security requirements and enabling integrated workflows of data management, curation, and analysis to amplify the intrinsic value of datasets. Its design should allow for expansion and continuous update in a secure environment, and easy adaptation in other health areas.

Advanced analytical and workflow tools (including AI-based) and, where relevant, predictive simulations should be proposed which enable improved analysis of the integrated patient data in combination with clinical insights and expertise to optimize best practice guidelines, support better clinical decision-making and assessment of outcomes for optimized care pathways, bespoke to the patient and the health care system.

Applicants should also consider how the proposed solutions could be part of integrated community-based health and social services that optimize independence, quality of life and wellbeing of the individual, while decreasing the burden on families and carers.

Applicants providing data as part of their applications should include in the proposals evidence that all legal, ethical, intellectual property permissions are in place to ensure the availability of the data to the consortium.

**Why the expected outcomes can only be achieved by an IHI JU project**

A cross-sectorial and multidisciplinary public-private partnership is needed to deliver the outcomes and impacts of this topic, fostering a trusted collaborative environment where the end-users integrate from day one with the innovation developers to ensure projects generate useful and usable outputs that will be sustained for longer term impact. Collaboration established between different healthcare industries can ensure inclusion of know-how and resources across different technological areas (for example, imaging, diagnostic, digital technologies, pharma) thereby fostering better crosstalk and
integration of multi-modal data and the delivery of meaningful converging technology-based innovations to improve healthcare. Contributions from industry partners should be integrated collaboratively with relevant interdisciplinary academic competences, including from the social sciences (for example health economics, ethics), and with resources like data registries and cohorts. Importantly, the future users of the proposed solutions (for example patients, their families and carers, regulators, health care professionals/providers) should also be included in the partnership from the start to ensure proper consideration of their needs and preferences to foster future implementation in the healthcare ecosystem. This should be supported by a key stakeholder mapping to grasp the relevant players within this ecosystem, while building and leveraging as much as possible upon already available resources and learnings.

**Indicative budget**

Applicant consortia should ensure that out of the total project budget, at least 45% needs to be covered by contributions provided by project participants, the rest being covered by financial contribution received from IHI JU (see call conditions for further information).

**Indicative duration of the actions**

Applicants should propose a project duration such that it matches project activities and expected outcomes and impacts.

**Dissemination and exploitation obligations**

To be determined