Themes that may be included in the first calls launched under the Innovative Health Initiative

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 Governing Board.

Single stage calls

Theme: Innovative patient-facing care pathways for patients with neurodegenerative diseases and comorbidities

Neurological disorders are the third most common cause of disability and premature death in the EU and their prevalence and burden will likely increase with progressive ageing of the European population, especially neurodegenerative diseases like dementias. The lack of effective disease-modifying treatments or cures for patients with neurodegenerative diseases underscores the challenges faced by patients and their families, as well as by the public healthcare systems. These patients also frequently display comorbidities (e.g. cardiovascular and metabolic types), and this together with the observed polypharmacy creates a highly complex system that needs better understanding.

A more holistic approach with thinking beyond traditional medical speciality silos is needed to improve interventions and better manage these comorbid patients with neurodegenerative diseases. This entails being dynamically informed of all aspects of the concomitant conditions and their interplay. Additionally, the patient perspective and notably their quality of life, needs more consideration. There are, however, insufficient tools that can integrate all these factors and help guide patients and their doctors in an individualised manner through the care pathway towards better health.

The projects funded under this theme are expected to deliver solutions to translate what is essentially a heterogeneous and fragmented set of complex, measurable and analysable data elements into a clinical decision support system that can guide patients to better health and quality of life.

Theme: Next generation imaging and image-guided diagnosis and therapy for cancer

Innovative solutions in personalised image-driven cancer diagnosis, planning, prognosis, therapy planning and outcome prediction are needed for the fight against cancer. Their achievement will require further enhancement of cancer patient imaging and other relevant data sources as well as artificial intelligence/machine learning (AI/ML)-enabled imaging and image-guided systems.

The eventual topic under this theme will aim to establish projects that would contribute to providing better AI/ML-supported tools and image-guided assistance for clinicians at the different steps of cancer care.

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The expected results/outputs should improve and enhance image-based diagnosis and therapy and enable more efficient patient-centric diagnosis/therapies/interventions, and better outcomes for patients. Finally, project outcomes would allow simplified clinical workflows, thus resulting in more precise therapeutic and interventional procedures for patients, reduced workload on staff, significant reduction of therapy and intervention time and shorter recovery times/hospital stays.

Theme: Precision oncology: Innovative patient-centric, multi-modal therapies against cancer

This theme focuses on biomarker-guided multi-modal precision oncology based on imaging, phenotype, genomics, *in vitro* diagnostics, co-morbidities, clinical and real-world data. Various industry sectors working together under IHI would need to come together and exchange knowledge and experience to align approaches with evidence generation.

It is expected that results from eventual projects funded under this theme would facilitate the development of new health technologies and integrate them with (possibly adapted) current therapy concepts, to create and explore multi-modal therapies personalised to the needs of the individual patient. In the eventual topic it is envisaged to pursue different therapeutic strategies and combine at least two cancer treating modalities. Depending on the specific therapies to be studied and combined, projects should evaluate aspects such as the sequencing, timing and dosing of therapies to maximise treatment effects with minimal toxicity and normal tissue complications.

Theme: Access and integration of heterogeneous health data for improved health care in diseases areas of high unmet public health need.

This theme aims to develop/further develop a scalable, open platform to access and integrate data from diverse sources including clinical trials; routine clinical care; patient reported outcome and experience measures; data generated by digital technologies such as sensors, wearables and mHealth apps in areas of high unmet public health need (final areas will be selected in consultation with the Science and Innovation Panel). A special focus will be put on novel datasets, e.g. datasets that are not already accessible for the purpose of medical decision-making, accompanied by adequate data quality measures.

Based on these data & platform, the projects funded under this theme should also develop/further develop patient-centred tools to facilitate disease self-management and tools to empower joint health care professional - patient decision making. In addition, clinical decision support systems to deliver better health care services should be developed/further developed. The added value of the platform and tools compared to the standard of care should be demonstrated through a use case applied to disease areas of high unmet public health need.

A strong exploitation & sustainability plan should be developed to ensure that all platforms and tools developed by projects have a long-term impact on all end users after the project(s) end including cross-border and cross-sector interoperability of the novel datasets to ensure synergies with other relevant health data initiatives.

Two stage calls

Theme: New tools for prediction, prevention and monitoring of cardio-metabolic diseases including secondary manifestations to enable timely intervention

Cardio-metabolic diseases are a major burden for society, patients, and relatives. There is an increasing need for earlier identification of individuals who are at increased risk of fast progression of their conditions to enable timely interventions.

The increased availability of and the ability to link more traditional and newer types of health data stemming from various sources (such as classical diagnostic screenings, *in vitro* diagnostics, 'omic molecular measurement technologies, wearable devices and digital health applications) opens up opportunities for detecting early signs of potential pathologies/health conditions. The ability to build more comprehensive and better integrated datasets will enable more timely diagnosis as well as detection of currently undiagnosed conditions, thereby paving the way for better health outcomes. Currently, the different types of useful data being generated are often isolated and accessible to only a small number of users. Therefore, there is the necessity to better link available data and de-fragment the field making the resulting databases accessible to users such as health care providers and researchers. These improved datasets will help unlock the potential of the data and enhance its overall utility.

For the project funded under this theme it is expected that the results will generate combined biomarkers to identify citizens at risk who are currently not detected, and patients at risk of fast progression of disease with an intended focus on atherosclerosis and heart failure including their secondary manifestations.

Theme: Strengthening EU clinical development excellence and innovation attractiveness: Harmonised methodology to promote the uptake of early feasibility studies (EFS)

The development of innovative / breakthrough health technologies takes a long time from bench to launch on the market and is incremental as to the design and intervention procedure.

To smooth the development processes of these health technologies, early testing through early feasibility studies could facilitate the transition towards pivotal studies by optimising the design of clinical investigations that would in turn facilitate patient access to potentially beneficial technologies including digital technologies. These early feasibility studies are not yet widely taken up in the EU, therefore the projects funded under this theme should contribute to the development of a methodological framework that will harmonise approaches and facilitate the uptake of early feasibility studies in the EU. They should also look at facilitating the interactions between the different stakeholders that would contribute to a strengthened patient-centred evidence generation and innovation ecosystem.

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