# IHI
# 1ˢᵗ Call for proposals

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# Introduction

The Innovative Health Initiative Joint Undertaking (IHI JU) is a partnership between the European Union and industry associations representing the sectors involved in healthcare, namely COCIR (medical imaging, radiotherapy, health ICT and electromedical industries); EFPIA, including Vaccines Europe (pharmaceutical industry and vaccine industry); EuropaBio (biotechnology industry); and MedTech Europe (medical technology industry).

IHI JU aims to pioneer a new, more integrated approach to health research and builds on the experience gained from the Innovative Medicine Initiative 2 Joint Undertaking (IMI2 JU).

IHI JU aims to translate health research and innovation into real benefits for patients and society, and ensure that Europe remains at the cutting edge of interdisciplinary, sustainable, patient-centric health research. Health research and care increasingly involve diverse sectors. By supporting projects that bring these sectors together, IHI JU will pave the way for a more integrated approach to health care, covering prevention, diagnosis, treatment, and disease management.

As current health challenges and threats are global, IHI JU should be open to participation by international academic, industrial and regulatory actors, in order to benefit from wider access to data and expertise, to respond to emerging health threats and to achieve the necessary societal impact, in particular improved health outcomes for Union citizens.

# Topics Overview

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| **IHI-2022-01-01**<br><br>**An innovative decision-support system for improved care pathways for patients with neurodegenerative diseases and comorbidities** | The maximum financial contribution from IHI JU is up to EUR 15 000 000<br><br>Applicant consortia should ensure that out of the total project budget, at least 45% needs to be covered by contributions provided by project participants | Research and Innovation Action (RIA)<br><br>Single-stage submission and evaluation process.<br><br>Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget availability and their ranking. |
| **IHI-2022-01-02**<br><br>**Next generation imaging and image-guided diagnosis and therapy for cancer** | The maximum financial contribution from IHI JU is up to EUR 40 000 000<br><br>Applicant consortia should ensure that out of the total project budget, at least 45% needs to be covered by contributions provided by project participants | Research and Innovation Action (RIA)<br><br>Single-stage submission and evaluation process.<br><br>Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget availability and their ranking.. |
| **IHI-2022-01-03**<br><br>**Personalised oncology: innovative people centred, multi-modal therapies against cancer** | The maximum financial contribution from IHI JU is up to EUR 40 000 000<br><br>Applicant consortia should ensure that out of the total project budget, at least 45% needs to be covered by contributions provided by project participants | Research and Innovation Action (RIA)<br><br>Single-stage submission and evaluation process.<br><br>Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget availability and their ranking. |
| **IHI-2022-01-04**<br><br>**Access and integration of heterogeneous health data for improved healthcare in disease areas of high unmet public health need** | The maximum financial contribution from IHI JU is up to EUR 40 000 000<br><br>Applicant consortia should ensure that out of the total project budget, at least 45% needs to be covered by contributions provided by project participants | Research and Innovation Action (RIA)<br><br>Single-stage submission and evaluation process.<br><br>Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget availability and their ranking. |

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

## 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, healthcare 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).

- A patient stratification able to better predict clinical outcomes to support the development of more patient-adapted interventions / therapeutics including that of 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[1]' by promoting better exchange of, and access to, different types of health data and data generated by health technologies (through FAIR principles: findable, accessible, interoperable, and re-usable) for the benefit of European citizens, health researchers and health policy makers.

## Expected outcomes

Research and innovation (R&I) actions to be supported under this topic must contribute to all of 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 (for example using a "sandbox" approach), 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, including

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[1] https://ec.europa.eu/commission/presscorner/detail/en/ip_22_2711

consideration for data management options and functionalities relevant for patients and/or family members.

- 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 (for example analytical tools and algorithms) able to provide (near) real time feedback on health interventions, including on the usability, efficacy/effectiveness, and 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 those multi-modal, multi-parametric (including socio-economic) data, which influence variations in the status of the patient with neurodegenerative disease and the required levels of care. This will benefit patients, who will receive more person-centric treatment and care. Meanwhile it will help healthcare providers to optimise the allocation of resources and predict 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 public healthcare 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. Recent developments give grounds for cautious optimism that a disease-modifying therapy is on the horizon. However, the high disease prevalence, and the complex evaluation process when such a therapy becomes available, will create challenges for already over-burdened healthcare systems. This will increase the demand for and importance of diagnostic and digital solutions that can drive the related clinical pathways and optimise and personalise care delivery.

The primary objective of this topic is to develop a decision-support system to enhance medical decisions with targeted clinical knowledge, patient information, and other health information for a more holistic (better integrating diagnosis, treatment and care and breaking silos across specialities) 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.

In their proposal, applicants should formulate how to best achieve all the outcomes/outputs of this topic, also describing the expected actual improvement in care and treatment outcomes and reflecting on aspects of implementation into routine care and sustainability, that are barriers to developing and distributing/delivering innovations. This should be preceded by a key stakeholder mapping to grasp the relevant players within this ecosystem and build and leverage as much as possible upon already available resources and learnings.

Proposals should address a patient population with a neurodegenerative disease where there is evidence of the importance of comorbidities in their healthcare pathways and on patient quality of life. The choice of the comorbidity should consider the burden for patients, carers and 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 the 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, for example on the socioeconomic environment as well as professional and informal caregivers (like availability, roles, interprofessional cooperation, interaction with the patient/client), the setting and organisation of care, staffing, and payment models, should be considered to enrich the dataset informing decision, as well as data from patient registries. Current European activities on digital health and care should be considered when relevant[2]. 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'. They should also give ample consideration for the control of data reuse by patients and healthcare professionals, for example by the implementation of 'FAIR' data principles and a suitable data governance structure.

The platform should build on suitable existing platforms or elements thereof (for example specialised research infrastructures, including those 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 the datasets. Its design should allow for future expansion as well as continuous updates in a secure environment, plus potential integration with other platforms and easy adaptation for use in other health areas.

Advanced analytical and workflow tools (including artificial intelligence (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 optimise best practice guidelines, support better clinical decision-making and assessment of outcomes for optimised care pathways, bespoke to the patient and the healthcare system.

Applicants should also consider how the proposed solutions could be part of integrated community-based health and social services that optimise independence, quality of life and the wellbeing of the individual, including when relevant behavioural changes, 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, and intellectual property permissions are in place to ensure the availability of the data to the consortium.

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[2] https://ec.europa.eu/health/ehealth-digital-health-and-care/electronic-cross-border-health-services_en

## Why the expected outcomes can only be achieved by an IHI 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, nursing sciences, health sciences/public health, psychology), and with resources like data registries and cohorts. Importantly, the future users of the proposed solutions (for example patients, their families and carers, regulators, healthcare 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.

## Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI up to EUR 15 000 000.

IHI estimates that an IHI financial contribution of around EUR 5 000 000 to 7 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia shall ensure that at least 45% of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.

Additional Activities from industry members and their constituent or affiliated entities may also contribute towards this 45% threshold, providing these activities are related to the project. Contributing partners do not contribute Additional Activities.

## Indicative duration of the actions

Applicants should propose a project duration that matches the project's activities and expected outcomes and impacts.

## Dissemination and exploitation obligations

The specific obligations described in the Conditions of the calls and calls management rules[3] under "Specific conditions on availability, accessibility and affordability" do not apply.

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[3] See section 4.2.3.2 of this amended Work Programme

# Topic 2: Next generation imaging and image-guided diagnosis and therapy for cancer

## Expected impacts to be achieved by this topic

- Patients benefit from improved diagnostic and therapeutic procedures and innovations better adapted to their individual health condition, while meeting the needs of the healthcare system.

- Contributing to the development of high-quality tools, high-quality data, advanced patient imaging and image-guided technologies and processes for improved early diagnosis, prognosis, staging, intervention planning, therapy and management of cancer and long term follow up.

- Including next-generation imaging technologies and image-guided solutions as part of combined cancer therapies (e.g., theranostics, chemotherapy, targeted therapy including immunotherapy, radiotherapy and/or surgery) through seamless integration of tools, data and algorithms into the care pathways.

- Enabling the development of improved artificial intelligence (AI) and machine learning (ML) validation and evaluation methodologies for imaging and image guided diagnosis and image-guided therapy for cancer.

- Better informed decision-making at different levels of the healthcare system that will in turn contribute to a better allocation of resources towards cost-effective innovations.

- Contributing to the objectives of Europe's Beating Cancer Plan and to the Horizon Europe Mission on Cancer and the initiatives in the Digital Europe Programmes.

## Expected outcomes

The proposals are expected to focus on image-based cancer diagnosis, prognosis, treatment planning and therapy. Project results must contribute to all of these expected outputs and outcomes:

- Expanded use of cancer patient imaging data sources, with improved data quality, annotation and computability, contributing to solutions that automatically link images to clinical data to improve diagnostic, staging, predictive and therapeutic tools for clinicians, including image-guided tools.

- Robust evaluation and validation frameworks for AI/ML-based algorithms applied to cancer patient images, to improve image-guided diagnosis, prediction of therapy outcome, planning and therapy of cancer patients.

- Healthcare professionals across Europe get access to advanced, easy-to-use solutions for minimally invasive interventions, guided by medical imaging for monitoring disease progression or treatment response, in combination with biomarkers and other relevant data.

- Improved image-driven planning and predictive tools that enable healthcare providers to facilitate diagnosis, treatment, and follow-up to improve patient outcomes.

- Novel, continuously self-learning, trustworthy, explainable AI/ML-enabled image guided diagnosis, therapy planning, and interventional systems used in clinics/hospitals and possible related benchmarks.

- Demonstrated added-value for end-users such as patients and carers, healthcare professionals, national health systems, and healthcare providers in using next generation imaging and image-guided diagnosis and therapy solutions for cancer.

- Enable seamless and successful further development of the concepts and solutions developed, leading to integrated products and services delivering proven benefits to patients, carers, healthcare systems and society as a whole.

## Scope

The specific challenge to be solved by this call topic is to provide early evidence of improved cancer patient care when using next-generation imaging technologies and image-guided solutions as part of combined cancer therapies. An optimised image-based care path from early diagnosis and screening to treatment and follow-up is essential to improve the outcome of cancer patients and help optimise clinical workflows and cancer patients' journey.

Innovative solutions in cancer diagnosis, therapy planning, interventions and outcomes can be achieved by pooling, linking, and using existing cancer patient imaging and other relevant data for the development of robust AI/ML-based algorithms and enhancing of image-guided tools in clinical settings. A key point underpinning the use of AI and ML in the fight against cancer is access to high quality data. Furthermore, there are limited recognised validation and performance evaluation frameworks for AI/ML-based diagnostic algorithms.

Within the framework of the European Cancer Imaging Initiative[4], and building on the results of other relevant research projects, the proposal should enable secure, General Data Protection Regulation (EU GDPR) compliant and interoperable access to cancer imaging data sources for the purpose of developing and/or enhancing new innovative features of AI/ML-enabled tools used for diagnosis, prognosis, therapy planning, intervention, and follow up. Proposals should also focus on understanding challenges and propose sustainable solutions to close gaps in algorithm validation and algorithm evaluation in the context of developing AI/ML-based tools for cancer diagnosis and outcome prediction.

The proposal should aim to improve AI/ML-enabled imaging and image guided solutions in order to assist and guide clinicians during diagnosis, staging, patient monitoring, therapy planning, intervention and follow-up. Where appropriate, proposals should demonstrate novel ways to interact with the imaging data. The driving principle must be improving and enhancing image-based diagnosis and therapy, e.g. through automated image interpretation and segmentation, quantitative disease assessment, intuitive treatment planning and smart guidance both during treatment itself and in post-treatment monitoring of response to therapy, to enable more efficient patient-centric diagnosis/therapies/interventions and better patient outcomes.

The proposed research and innovation (R&I) activities should result in simplified clinical workflows, for instance through enhanced or complementary robotic-assisted procedures, thus resulting in more precise therapeutic and interventional procedures for patients, reduced workload on staff, a reduction in therapy planning and intervention time, and shorter recovery times/hospital stays.

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

To take advantage of the potential synergistic effects of next-generation imaging technologies and image-guided solutions being part of combined cancer therapies, it is essential that different industry sectors

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[4] This initiative is part of the Europe's Beating Cancer Plan: https://eur-lex.europa.eu/legal-content/en/TXT/?uri=COM:2021:44:FIN

come together, exchange knowledge and experience, and find optimal solutions. Combining expertise from various sectors is critical to the success of this proposal.

This cross-sectorial collaboration is expected to include academia and health care specialists to leverage innovative and novel image-guided concepts in diagnostic and therapeutic applications.

This will ensure the clinical relevance of technical and scientific innovations. IHI provides a unique opportunity to break down existing silos to enable faster development of people-centred, safe, effective, cost-effective, and affordable health solutions.

## Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI up to EUR 40 000 000.

IHI estimates that an IHI financial contribution of around EUR 10 000 000 to 20 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia shall ensure that at least 45% of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.

Additional Activities from industry members and their constituent or affiliated entities may also contribute towards this 45% threshold, providing these activities are related to the project. Contributing partners do not contribute Additional Activities.

## 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

The specific obligations described in the Conditions of the calls and calls management rules[5] under "Specific conditions on availability, accessibility and affordability" apply.

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[5] See section 4.2.3.2 of this amended Work Programme

# Topic 3: Personalised oncology: innovative people centred, multi-modal therapies against cancer

## Expected impacts to be achieved by this topic

In addition to contributing to Europe's Beating Cancer Plan, the Mission on Cancer, the EU Industrial and Pharmaceutical Strategy, and implementation of the Sustainable Development Goals of the United Nations, the work supported under this topic will help to achieve several of the expected impacts from IHI specific objective 2: "Integrate fragmented health research & innovation (R&I) 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."

Specifically, it will do this by doing the following:

- Breaking down fragmentation between various disciplines of medicine and technological areas in order to conceive and develop technologically and socially innovative, people-centred, integrated healthcare solutions that can seamlessly be introduced in healthcare systems.

- Fostering the development of safe and effective innovative health technologies and their combinations thanks to new and harmonised approaches to data generation.

- Better and faster integration of future products, services and tools along the healthcare pathway responding to patients' specific needs and leading to improved health outcomes and patient well-being.

Moreover, the work supported under this topic will also contribute to some expected impacts from IHI Specific Objective 3: "Demonstrate the feasibility of people-centred, integrated health care solutions."

- Patients benefit from treatment and care better adapted to their needs through improved diagnostics, prognosis and monitoring their quality of life while on and beyond treatment.

- Integrated health care solutions, including those based on the use of digital solutions, better responding to the needs and preferences of patients and healthcare providers through an inclusive approach.

- Successful implementation of digital solutions supporting people-centred care.

## Expected outcomes

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

*Platform, standards and regulatory*

- A versatile and dynamically evolving platform for R&I collaboration across sectors, between academia and industry partners with a focus on the early stages of applied clinical research on cancer.

- Cancer healthcare pathway standards to enable personalised treatment and joint registries.

- Demonstration of how the benefits of health technology convergence can be harnessed in line with all relevant regulatory frameworks in Europe.

*Improved multi-modal therapy*

- Health innovations in cancer therapy through development, testing and validation of multi-modal therapeutic approaches including novel or emerging technical and clinical concepts and potentially supported by in vitro diagnostics.

- Personalised therapeutic options for cancer patients to improve outcomes, including shared information and integration of various specialised clinicians as well as shared decision-making for treatment and care.

- Improved active monitoring and adaptation of therapy through the patient journey, involving early-response biomarkers and evaluation of their predictive power and correlation to clinical outcomes, as well as more involvement of patients in the cancer patient journey.

## Scope

Different treatment modalities are available for various cancers, however, the differing biology of cancers as well as the differing efficacy of treatment modalities dictate rather patient-specific approaches. Multi-modal therapies have been shown to be of high value in this respect and there is a strong need to increase the therapeutic arsenal of such multi-modal therapies and to tailor the treatment approach to the individual patient.

The aim of this call topic is biomarker-guided multi-modal precision oncology based on imaging, phenotype, genomics, *in vitro* diagnostics, co-morbidities, clinical and real-world data.

Proposals should 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. Applicant consortia should pursue different therapeutic strategies and combine at least two cancer treating modalities[6] (supported by a sound scientific rationale in the application).

The proposed R&I activities should include development of research protocols for multi-modal therapies expected to have a significant potential to create patient benefits. These protocols should be explored via early clinical studies with sufficient sample size and statistical power to assess safety and efficacy and demonstrate feasibility of the chosen multi-modal approach.

Depending on the specific therapies to be studied and combined, the R&I activities should consider the clinical decision-making process aspect among the various disciplines involved. They should also include the evaluation of aspects such as the sequencing, timing and dosing of therapies to maximise treatment effects with minimal toxicity and normal tissue complications. It is expected that the use of prognostic and predictive biomarkers and the combination of diagnostic tools to plan and adapt treatment and evaluate treatment and the follow up of patients will be a key component of the proposed integrated healthcare solutions.

To overcome the barriers to cross-sectoral collaboration, proposals need to consider methodologies and standards for the combination of various technologies into integrated healthcare solutions. Furthermore,

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[1] Pharmaceutical, nanotechnology, radiology or other therapeutic approaches (e.g. small molecules, hormone-, cell-, or immuno-therapy, drug delivery systems and nanoparticles, radio-ligand therapy, adaptive radiation therapy with guided dose optimisation, altered dose fractionation schemes including hypo-fractionation, ablation and radio-surgical concepts based on photon or charged particle radiation including FLASH (irradiation at ultra-high dose rates, several orders of magnitude higher than conventional dose rates), theranostics and radiopharmaceuticals).

proposals should also consider the design and conduct of clinical studies of multi-modal therapies and methods to evaluate their safety and clinical benefits.

Proposals should include a description of how data will be generated, captured and stored, and how it will be used in line with the FAIR[7] principles and sustained to promote collaboration among stakeholders. Proposals should enable secure, GDPR[8] compliant and interoperable access of the data.

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

Rapid scientific and technical progress in medicinal products, diagnostics, medical devices, and complementary services have created the potential for significant improvements in healthcare. However, the opportunities for developing integrated, interoperable health care solutions can only be fully harnessed if barriers to cross-sectoral collaboration and to collaboration with patients, carers and healthcare professionals are overcome.

To realise the potential synergistic effects of biomarker-guided multi-modal precision oncology based on imaging, phenotype, genomics, *in vitro* diagnostics, co-morbidities, clinical and real-world data, it will be necessary for different industry sectors to come together and exchange knowledge and experience, and to find optimal combinations of the various solutions they can provide. Moreover, this cross-sectorial collaboration must be extended to academia and healthcare providers to leverage innovative clinical concepts that they can offer, and to ensure the clinical relevance of technical and scientific innovations. IHI provides a unique opportunity to break down existing silos to enable faster development of people-centred, safe, effective, cost-effective and affordable health solutions.

## Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI up to EUR 40 000 000.

IHI estimates that an IHI financial contribution of around EUR 10 000 000 to 20 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia shall ensure that at least 45% of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.

Additional Activities from industry members and their constituent or affiliated entities may also contribute towards this 45% threshold, providing these activities are related to the project. Contributing partners do not contribute Additional Activities.

## 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

The specific obligations described in the Conditions of the calls and calls management rules[9] under "Specific conditions on availability, accessibility and affordability" apply.

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[7] Findable, Accessible, Interoperable, Reusable

[8] General Data Protection Regulation

[9] See section 4.2.3.2 of this amended Work Programme

# Topic 4: Access and integration of heterogeneous health data for improved healthcare in disease areas of high unmet public health need

## Expected impacts to be achieved by this topic

This topic aims to achieve the following:

- Better and faster integration of future products, services and tools along the healthcare pathway, responding to patients' specific needs and leading to improved health outcomes, patient safety and patient well-being.

- Wider availability of interoperable, large scale, quality data, respecting FAIR principles[10], facilitating research and the development of integrated products and services.

- Advanced analytics/artificial intelligence (AI) supporting health research & innovation, resulting in:
  a) clinical decision support for increased accuracy of diagnosis and efficacy of treatment;
  b) wider availability of personalised health interventions to end-users;
  c) better evidence of the added value of new digital health and AI tools, including reduced risk of bias due to improved methodologies.

## Expected outcomes

Proposals under this topic should aim to deliver results that contribute to all of the following expected outcomes for a specified disease area of high unmet public health need:[11]

- Researchers, including industry stakeholders, have long-term access to diverse data at scale, enabled by the linkage and integration of novel and cross-sectoral sources, including industry sources. If possible, some of these data should be able to be used for providing evidence to support regulatory decision-making.

- Researchers, including industry stakeholders, have long-term access to new tools that enable the integration and analysis of these data. If possible, some of these tools should be able to be used for providing evidence to support regulatory decision-making.

- Citizens, including patients, are given user-friendly, interoperable tools to access their own health data from different sources to support disease self-management and empower joint health care professional - patient decision making.

- Health care professionals and healthcare providers[12] have access to integrated data from diverse sources and clinical (and other) decision support systems to deliver better healthcare services to patients and populations in the most suitable and efficient manner.

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[10] Wilkinson, M., Dumontier, M., Aalbersberg, I. *et al.* The FAIR Guiding Principles for scientific data management and stewardship. *Sci Data* **3,** 160018 (2016). https://doi.org/10.1038/sdata.2016.18

[11] Unmet public health needs are needs currently not addressed by healthcare systems for various reasons, for example if no medicines are known to treat a disease. Areas of public health importance are those where the burden of disease is high for patients and society due to the severity of the disease (in terms of mortality, physical and functional impairment, comorbidities, loss of quality of life…) and/or the number of people affected by it. For example, Alzheimer's disease.

[12] The term 'healthcare providers' refers to organisations that deliver healthcare goods and services. Typical healthcare providers are hospitals, long-term care facilities, providers of ambulatory healthcare, laboratories, nursing care facilities, pharmacies and so on.

## Scope

Over the past few years, there has been an explosion in the generation of data that could be harnessed for use in healthcare delivery and research. These data include data generated by digital technologies and patient reported outcome and experience measures, as well as data from clinical trials and routine clinical care. However, accessing, integrating & analysing these data to maximise the value for patient care and research is extremely challenging.

This topic aims to provide a scalable platform for the seamless integration or linkage of these diverse data at scale, and develop tools to allow the data to be used in clinical care, patient self-management and research in disease areas of high unmet public health.

For their proposed activities applicants should **clearly identify a disease area** of high unmet public health need,[13] taking into account comorbidities and/or functional status, and **explain their choice** with empirical evidence where possible**.**

**For the selected disease area, the project(s) funded under this topic are expected to:**

- **Develop / further develop a scalable, open platform** for the seamless integration or linkage of data at scale from diverse public and private data sources relevant to the disease area selected. These data sources should, as a minimum, include all of the following: clinical trials; registries; patient safety data; routine clinical care; publicly available health insurance data; patient reported outcome and experience measures; and data generated by digital technologies such as sensors, wearables and mHealth apps. Preferably, projects should also integrate data that has not usually been used before for the purpose of medical decision-making.

- Develop / further develop **tools focused on the needs of patients**, leveraging these diverse data sources to support patient self-management and empower joint healthcare professional - patient decision making.

- Develop / further develop **clinical (and other) decision support systems** leveraging these diverse data sources to allow clinicians to deliver better healthcare services to patients in the disease area selected.

- Demonstrate the **added value of the platform** and tools compared to current approaches through a use case (study) applied to the disease area selected.

- Demonstrate the widespread applicability and scalability of the platform & tools using data sources from outside of the project

- Publish sufficient information, including access protocols, on the data that has been used in the project to **facilitate long-term access and re-use**, while ensuring compliance with the General Data Protection Regulation and other relevant European legislation.

  Applicants should also aim to deliver the following:

- Public release of a set of minimum technical requirements for the developed platform/tools that includes interoperability, connectivity, data protection, cybersecurity and authentication/identification

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[13] Unmet public health needs are needs currently not addressed by healthcare systems for various reasons, for example if no medicines are known to treat a disease. Areas of public health importance are those where the burden of disease is high for patients and society due to the severity of the disease (in terms of mortality, physical and functional impairment, comorbidities, loss of quality of life…) and/or the number of people affected by it. For example, Alzheimer's disease.

requirements that need to be met to allow the efficient integration of additional data from new devices/sensors/sources into the decision-support system after the project ends.

- Sustainable, ideally open-source tools that help ensure the quality and FAIRness[14] of data at source (e.g., automated tools to help data entry, semantic coding, and data management in particular in registries and databases maintained by healthcare professionals/providers and research institutions) as well as methodologies, quality standards and metrics to assess data quality.

- Sustainable tools to increase cross-border and cross-sector interoperability of health data from the diverse sources mentioned above. Ideally, these tools use open exchange formats and take into account relevant EU initiatives including the eHealth Digital Services Infrastructure (eHDSI)[15] and the European Electronic Health Record Exchange Format (EEHRxF)[16].

- Sustainability plan/business model to ensure the long-term impact of the project results.

**Other considerations:**

- Applicants should **build on clearly identified existing tools & platforms** where possible, and ensure that the platform and tools developed can be applied to other disease areas or be relevant for other scientific and clinical communities (i.e. ensuring interoperability with other solutions). If applicants choose to develop a new data platform, a strong justification must be provided.

- Applicants must demonstrate that they have **access to sufficient diverse data**, including from industry sources, to meet the objectives of this topic. The data sources (name & country), types, and size must be described in the proposal alongside convincing evidence that the consortium will have access to these data for the project implementation.

- During their activities, applicants should ensure appropriate **engagement of the end-users** of the developed tools, especially **patients and healthcare professionals**.

- Applicants are expected to explore the integration of the outputs with the **European Health Data Space (EHDS)**[17] when it becomes operational, and explore synergies with other relevant health data initiatives and projects.

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

The data to be integrated in the funded projects are expected to come from diverse public and private sources. To access, understand and integrate these data and to develop platforms and tools for clinical decision-making and patient self-management requires significant cross-sectoral expertise including from patients, carers, health care professionals, healthcare data specialists, legal experts, academic researchers, SMEs, pharmaceutical and medical technology industries. These different public and private stakeholders will need to work closely together to achieve the objectives of this topic.

## Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI JU up to EUR 40 000 000.

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[14] FAIR data are data which meet principles of findability, accessibility, interoperability, and reusability.

[15] https://ec.europa.eu/health/ehealth-digital-health-and-care/electronic-cross-border-health-services_en

[16] https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format

[17] https://ec.europa.eu/health/ehealth/dataspace_en

IHI JU estimates that an IHI JU financial contribution of around EUR 20 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia shall ensure that at least 45% of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.

Additional Activities from industry members and their constituent or affiliated entities may also contribute towards this 45% threshold, providing these activities are related to the project. Contributing partners do not contribute Additional Activities.

## 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

The specific obligations described in the Conditions of the calls and calls management rules[18] under "Specific conditions on availability, accessibility and affordability" do not apply.

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[18] See section 4.2.3.2 of this amended Work Programme