

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.

Topic 3: Transforming healthcare delivery through integrated, scalable and patient-centred care systems

Expected outcomes

Actions under this topic are expected to contribute to the following outcomes:

- Interoperable solutions, that enable the integration and deployment of innovative technologies (including medical devices, diagnostics, imaging, monitoring, digital health and AI-enabled solutions as well as care-enabling technologies and data-driven clinical decision support systems), therapies and any health-related data into healthcare practice to support comprehensive, personalised, end-to-end patient-centred care pathways, benefitting patients and the relevant stakeholders in the healthcare ecosystem.
- Development of outcome-driven, value-based healthcare models to inform decision-making and support broader reimbursement across different European regions and care settings.
- A strategy to support adoption of integrated care innovations across Europe, addressing key system-level enablers, such as the HealthData@EU infrastructure, as well as barriers, including regulatory and Health Technology Assessment (HTA) constraints.
- A strategy for the deployment of decentralised, community-based or near-patient care approaches to improve access to advanced personalised interventions and high-quality care services for patients outside major centres and reduce geographic or socio-economic health inequalities while strengthening healthcare system resilience.

Scope

European healthcare systems need to transform into more resilient, data-driven and value-based systems that improve health outcomes, increase efficiency and ensure equitable access to innovation. A key challenge is to strengthen their sustainability and readiness to adopt, implement and scale effective innovations in line with European health policy objectives.

This requires better integration of diagnostic and care solutions, as well as more coordinated decision-making and delivery across the care continuum (end-to-end), so that effective interventions can be introduced and used optimally, promptly and consistently in real-world healthcare settings across Europe. This is especially needed for high-burden and high-complexity care areas where integrated diagnostics, monitoring, timely referral and longitudinal care pathways can significantly improve access and outcomes. Such areas include chronic diseases like cardiovascular, cancer, diabetes, respiratory, infectious diseases, neurological and neurodegenerative diseases, as well as other unmet public health needs such as mental health and women's health that remain under-addressed in health research and innovation. Furthermore, the care pathway should be optimised in acute, critical settings, and adapted for vulnerable populations, such as children and the elderly.

Accordingly, applicants must assemble a collaborative public-private partnership consortium reflecting the integrative and cross-sectoral nature of IHI JU to address the overall aim of the topic. The overall aim of this topic is to design, validate, and demonstrate scalable, integrated, patient-centred care models that connect the full continuum of healthcare delivery—from community-based prevention and early detection to timely diagnosis, optimal treatment, and long-term management in one or more of the above care areas. These models should enable integration of innovative medical technologies (such as medical devices, in vitro diagnostics (IVDs), imaging and monitoring solutions, remote patient management, AI decision support, clinical informatics platforms, etc), medicines, diagnostics, biomarkers and digital solutions to foster novel personalised approaches across the care pathway combining key building blocks of integrated care: prevention, diagnosis, intervention, monitoring and adaptive care management. These models should also facilitate interoperable system solutions that can operate across diverse healthcare settings.

Proposals should build on solutions, assets or components that have reached sufficient maturity to support implementation in routine or routine-like care, while allowing targeted development, integration and adaptation where needed.

In this context applicants should generate real-world evidence to support the adoption, scale-up and deployment of innovative medical technologies, diagnostics, medicines, and digital-health solutions, demonstrating their clinical, operational, and economic value. Where relevant, solutions should incorporate evidence-based approaches to support adoption, engagement, adherence and sustained use by patients, caregivers and healthcare professionals, facilitate their effective integration into routine clinical workflows and generate evidence for health-economic, clinical and operational value assessment. This could include demonstration of value in high-burden acute settings (e.g. surgery and critical care) and for extendibility across the care continuum. Patients, carers and healthcare professionals should be actively involved in the co-design, governance, implementation and evaluation of the healthcare models.

To successfully address the overall aim of this topic, applicants should include considerations in their proposals regarding the development of workflows to operationalise the European Health Data Space (EHDS), ensuring interoperability and secure data sharing to enable the integration of health technologies (medical devices, diagnostics, imaging and monitoring systems, digital tools, Electronic Health Records and registries) across different care settings as well as effective care coordination (primary and secondary use of health data). Applicants should build on existing infrastructures and standards wherever possible. For example, applicants should consider testing the different workflows, capabilities and services that the HealthData@EU infrastructure offers in accordance with the EHDS legal basis.

Applicants should demonstrate the potential for solutions to be scaled, sustainable and transferrable across different European regions and care settings, considering relevant implementation pathways. In this context, applicants should also consider as relevant operational, organisational and workforce strategies to embed innovative care pathways, medicines, medical technologies, diagnostics and digital health solutions into routine practice. These strategies may include workflow redesign and co-design, role definition, training, feedback mechanisms and monitoring of unintended consequences associated with implementation.

In addition, applicants should identify key system-level enablers and address barriers to the successful adoption of integrated care innovations. This includes different levels of digitalisation, regulatory constraints, supportive payment, procurement and reimbursement models for cross-sector interventions; and alignment with national HTA frameworks to facilitate patient access across Member States. Early active involvement of relevant providers, payers, HTA bodies and public authorities should support sustainable uptake.

Applicants are expected to consider the potential regulatory impact of the results and, as relevant, develop a regulatory strategy and interaction plan for generating appropriate evidence as well as engaging with regulators in a timely manner (e.g. EU national competent authorities, notified bodies for medical devices and in-vitro diagnostic devices, health technology assessment (HTA) agencies, and the European Medicines Agency (EMA) through existing opportunities for regulatory support services, such as the Innovation Task Force and qualification advice.

Expected impacts

Actions to be funded under this topic are expected to achieve the following impacts:

- Improved coordination and integration of care across the full patient journey, resulting in more timely diagnosis and interventions, improved long-term patient follow-up, optimised therapy sequencing, and iterative evidence feedback loops that enhance better outcomes across diverse patient populations.
- More sustainable, resource-efficient and resilient healthcare systems enabled by interoperable and data-driven infrastructures, reducing unnecessary hospitalisations, optimising resource use and supporting decentralised, community-based care in line with EU priorities, including the European Green Deal.
- Reduced inequalities in access to healthcare and innovation across regions and populations.
- Progress towards patient-centred, value-based and outcome-focused healthcare systems through informed decision-making and broad reimbursement across Europe.
- Faster and more predictable evaluation and deployment of innovative health interventions in clinical practice and scaling of integrated care models across different EU health systems contributing to enhanced European leadership in innovative healthcare delivery.

Actions funded under this topic are expected to consider and contribute to EU programmes, initiatives and policies, such as the Safe Hearts Plan, the EC's Strategy for European Life Sciences, the European Health Data Space (EHDS) and the European Partnership on Transforming Health and Care Systems (THCS).

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

Science and technologies are changing rapidly, and their successful implementation requires increased cross sectoral integration of technologies, know-how, products, services, and workflows for delivering people-centred healthcare. Laying the groundwork for the integration of innovative tangible health solutions that are suitable for end-users requires expertise, resources, and knowledge from all stakeholders in the innovation value chain.

IHI JU provides a unique framework to stimulate collaboration and leverage resources, bringing together the private (pharma and medical technology industry sectors) and public partners (academia, healthcare professionals and providers, patients and carers, regulators, health technology assessment bodies, payers, public health authorities) as well as small and medium-sized enterprises (SMEs), charitable foundations / philanthropic organisations, with a view towards ensuring that the developed solutions are comprehensive, evidence-based, and aligned with public health needs whilst offering new market opportunities to companies.

Indicative budget

The maximum financial contribution from the IHI JU is up to EUR 41 041 000. **NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.**

IHI JU estimates that an IHI JU financial contribution up to EUR 15,000,000 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 must ensure that at least 45 % of the action's eligible costs and costs for the action-related additional activities are provided by in-kind contributions to operational activities ('IKOP'), financial contributions ('FC's), or in-kind contributions to additional activities ('IKAA'). While 45 % is the threshold for eligibility, applicant consortia are strongly advised to aim for 50 % to provide a margin e.g. for unforeseen changes during the project lifetime.

IKOP and FCs may be contributed by the constituent and affiliated entities of both the private members and the contributing partners. IKAA may be contributed by constituent and affiliated entities of the private members only. Contributing partners and their affiliated entities cannot contribute IKAA. See the call conditions in the annual Work Programme for further information (also in the document "call text" published on the IHI website).

Indicative duration of the action

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 call management rules under 'Specific conditions on availability, accessibility and affordability' do not apply.

Glossary

Acronym	Meaning
AI	Artificial Intelligence
EHDS	European Health Data Space
EMA	European Medicines Agency
EU	European Union
FCs	Financial Contributions
HTA	Health Technology Assessment
IHI JU	Innovative Health Initiative Joint Undertaking
IVDs	in vitro Diagnostics
IKAA	in-kind contributions to additional activities
IKOP	in-kind contributions to operational activities
SMEs	Small & Medium-sized Enterprises