Strategic Research and Innovation Agenda
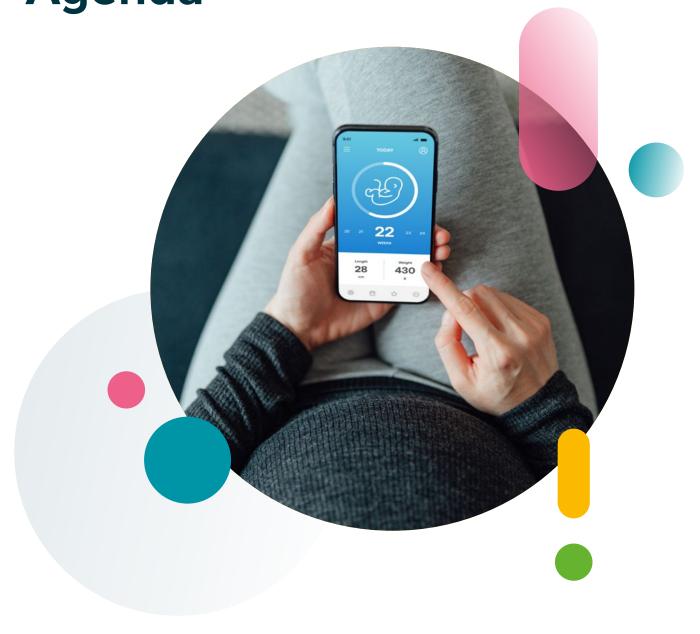
The Innovative Health Initiative Joint Undertaking (IHI JU) aims to enable the cross-sectoral integration of technologies, know-how, products, services and workflows for people-centred healthcare.

Its ambition is to support the delivery of timely and well-substantiated prevention, diagnosis, and treatment. The partnership aims to help keep EU citizens in good health, decrease disease burden for patients, care givers and healthcare professionals. It intends to contribute to the sustainability and resilience of healthcare systems and to the competitiveness of European health industries.

This document was prepared jointly by the IHI JU member industry associations and the European Commission services and with the support of the IHI JU Programme Office.

Contents

CHAPTER 1

Vision of the Innovative Health Initiative

Healthcare in Europe faces multiple challenges

Europe has always strived to deliver high standards of healthcare. At the same time, health is a constant and major concern for many Europeans, the EU has an ageing population and a rising burden of related diseases, notably non-communicable diseases (for example cardiometabolic diseases, cancers, neurodegeneration, or musculoskeletal disorders). Most countries struggle with long-term expenditure and workforce planning in healthcare and this problem grows as the age pyramid changes. The healthcare expenditure in EU countries is steadily increasing and in 2017 it accounted for nearly 10% of EU Gross Domestic Product (GDP), most of which originated from public sector spending (7%) ([1]). This challenges the long-term sustainability of EU healthcare systems, which are under increasing fiscal and organisational pressures.

The COVID-19 health crisis exacerbated the challenges that European healthcare systems face in detecting, combatting, and managing outbreaks of infectious diseases in a coordinated manner. Simultaneously, the relentless work from the research community which led to the availability of several COVID-19 vaccines in record time, provides evidence of the critical importance of collaborative R&I to respond rapidly to emerging health threats, as well as of the strategic value of public-private partnerships.

A significant contribution to addressing the challenges in healthcare comes from innovative healthcare interventions that facilitate patient access to healthcare across the EU. However, such interventions are notoriously

_____

([1]) https://ec.europa.eu/eurostat/statistics-explained/index.php/Healthcare_expenditure_statistics#Healthcare_expenditure

complex to design and even more so to implement, as they may stretch over the full spectrum of the healthcare pathway: from prevention through diagnosis and treatment, through to disease management including long-term and palliative care. Innovation in healthcare is today based on both use and convergence of established and innovative technologies (including medicinal products, medical devices, *in-vitro* diagnostics, blood-tissue-cell-based therapies, digital technologies with artificial intelligence, robotics, nanotechnologies, etc.). Fostering such convergence of technologies will enable the development of cross-sectoral innovations that are better able to respond to people's needs. Such an approach will also facilitate the integration of health interventions developed by different industrial sectors along the healthcare pathway. The goal is a more targeted intervention strategy leading to personalised treatments and improved individual health outcomes. To fully exploit the potential of various technologies and approaches, existing silos must be broken down across discovery science and translational research as well as between different academic research disciplines and industry sectors. This will enable faster development of people-centred, safe, effective, cost-effective and affordable health solutions. To achieve this, it is crucial to involve all stakeholders, including citizens, in the co-design, co-development and co-implementation of those innovative solutions. The development of cross-sectoral integrated solutions also requires the establishment of a constructive, trusted, and continued dialogue between industry sectors and regulators.

In a global context, the EU has leading healthcare systems and is a strong global actor in health research. However, it is still relatively weak in translating research results into tangible health products, services, and solutions, which are delivered to the market and taken up by healthcare systems in Europe. This can partially be attributed to insufficient early consideration of societal and/or user needs. Therefore, patients and end-users need to be involved in all stages of research, from project design through to implementation, in order to develop meaningful innovations.

Strengthened collaboration between industry sectors, academia and public authorities will not only offer better opportunities to respond to public health needs in Europe, but also provide a strong base to launch, grow, retain, and attract competitive companies in Europe.

New science and technologies have yet to gain traction

Medical science and practice are becoming increasingly interdisciplinary, integrating bioinformatics, biomechanics and biochemistry, chemistry, physics, mathematics, biology, micro-electronics and nanotechnologies, as well as social and behavioural knowledge. Additionally, without leveraging the full potential of data and digital tools, a significant opportunity is missed for Europe to lead understanding of complex, multifactorial diseases as well as complex interdependencies between diseases in an aging society.

Causal factors of many diseases are still poorly understood, notably the interplay between genetic and environmental factors. Deciphering their impact on disease onset and course, as well as on treatment success, remains a long-term desirable target in healthcare.

Recent developments in EU digital health policy, such as the European Health Data Space initiative, are making steps to address the current gaps, however the potential of (big) data in terms of public health and healthcare innovation remains largely untapped due to low interoperability and interconnectivity, inconsistent standards, poor data quality, lack of validated approaches and methods for processing and analysing this data, missing skills, and know-how to handle and interpret the data.

Whilst the EU has benefited from a strengthened framework on data protection, uncertainties remain on the practical implementation of requirements for e.g., secondary use of health

data, which creates additional complexity. For researchers, the biggest challenge is to access meaningful data at a large scale in a timely and cost-effective manner. Furthermore, data security, data privacy, in addition to scientific and ethical considerations must be duly taken into account when developing data access and exchange protocols, FAIRification anonymisation processes and analytics tools, including artificial intelligence assets.

Building on lessons learned

The Innovative Health Initiative (IHI) builds on lessons learned from IMI2 Joint Undertaking (IMI2 JU), a public-private partnership between the EU and the European pharmaceutical industry, based on Article 187 TFEU. IMI2 JU was established under Horizon 2020, as a continuation from its predecessor IMI JU which was established under Framework Programme 7. Close to €5 billion has been committed to the two initiatives between 2008 and 2020, making it one of the world's largest public-private partnerships (PPPs) to accelerate drug development [2]. At the same time, IHI is not meant to be a direct continuation of IMI2 JU. Rather, IHI will build on IMI results and ongoing initiatives within a new platform with broader scope, partners and stakeholder base.

IHI also builds on the learnings from the health activities in the ECSEL JU, which focus primarily on the enabling electronics components and systems. Moreover, there are several health-related activities pursued under the ECSEL JU, such as the establishment of pilot production lines for smart medical devices and implants involving diverse MedTech actors, which are of high relevance for future activities under IHI.

This partnership reflects the importance of the full spectrum of health technologies, as well as the progress in convergence of health technology areas and a significantly more prominent role for digital technologies and data analytics in health research than when IMI2 JU was established. IHI will thus be responding to the recommendation of the IMI2 JU interim evaluation to "enable the active engagement of other industry sectors with the pharmaceutical industry" [3]. A key element for linking all these industry sectors is the necessity to avail of, and share, data involving innovative digital tools in order to perform people-centred translational R&I for the benefit of the European people and health systems.

---

[2]   DG RTD (2019), Inception Impact Assessment of the Analysis of the network structure of the current partnerships (Social Network Analysis) European Partnership on Innovative Health.

[3]   European Commission (2017), The Interim Evaluation of the Innovative Medicines Initiative 2 Joint Undertaking (2014-2016) operating under Horizon 2020. Experts Group Report. Luxembourg: Publications Office of the European Union

Objectives

The Innovative Health Initiative will focus on cross-sectoral approaches to facilitate the creation of new products and services to prevent, intercept, diagnose, treat and manage diseases and foster recovery more efficiently. The goal is to lay down foundations for the development of safer and more effective healthcare products or solutions that respond to unmet public health needs and that can be implemented into healthcare systems. This includes optimising the treatment quality, duration and outcome, providing the right intervention to the right patient at the right time.

The IHI JU aims to achieve the following **general objectives** by 2030:

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 healthcare products or services, with demonstrated suitability for uptake by healthcare 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.

Activities and resources

Activities will consider the different innovation cycles of pharmaceutical and medical technology industries. While R&I processes towards novel medicines are complex, lengthy and highly regulated, integrated pre-competitive activities, including demonstration pilots, could accelerate and improve this process. Most activities will be cross-sectoral, reflecting the integrative nature of the Partnership.

Overall, IHI will cover a variety of activities of the health innovation chain including, but not limited to:

1. discovery of new molecules, mechanisms of action, processes, technologies;

2. development and testing of these discoveries;

3. development of methodologies for assessment of safety, health outcomes or health-economic evaluation;

4. pre-standardisation activities;

5. contribution to regulatory science;

6. pilots/proofs of feasibility including *in-silico* trials.

The research supported by this public-private partnership should remain at pre-competitive level and is not aimed at delivering products or services directly within healthcare systems or on the market.

The following features will be at the core of IHI:

1. A multi-sector initiative, including the pharmaceutical and medical technology sectors, which will secure these sectors' expertise and active engagement into the development of new healthcare interventions;

2. People-centric, rather than product- and pathology-centric, goals – the focus will be the patient and citizen journey through healthcare, with the help of the most suitable health technologies and social innovations and taking account of demographic trends;

3. Early engagement with public sector stakeholders for the definition of priorities will be ensured by creating the 'Science and Innovation Panel', involving relevant public and private stakeholders from the healthcare ecosystem. This will also ensure that IHI projects will better reflect the needs of healthcare systems, including cross-border scenarios;

4. Sustainability and impact of the projects will be increased by setting concrete performance and impact targets as part of project design. This greater understanding of impact will bring enhanced clarity on the follow-up and uptake (in collaboration with end-users, regulators, HTA bodies and payers, and relevant European Research Infrastructures);

5. Openness and inclusiveness will be secured by incentivising and facilitating participation and contributions from industries, charities, foundations and other entities which are not part of the JU founding members, via the "Contributing Partners" status;

6. Clear focus on translational research or translational research enablers. This includes raising the quality and efficiency of activities to deliver reproducible and validated evidence and assets compliant with standards governing scientific, regulatory, and economic evaluation of future products, services, and their combinations. IHI will work to reach its objectives with the following resources:

- up to EUR 1.2 billion provided by the European Union (from the Horizon Europe Health Cluster),

- at least EUR 1.0 billion provided by the member industry associations,

- up to EUR 200 million from Contributing Partners.

The above figures include up to EUR 60.4 million for administrative costs, borne equally by the EU and by member industry associations.

The breakdown of resources to specific IHI activities will be decided by the IHI Governing Board when adopting annual work programmes, taking into account advice from the States Representatives' Group and of the Science and Innovation Panel as the formal advisory bodies of the IHI JU. The description of specific activities and allocated resources will be provided in annual activity reports which will be made publicly available on the IHI website. The annual activity reports will also report on the Key Performance Indicators used to monitor progress towards reaching IHI objectives, with specific baselines and targets [4].

---

[4] At the time of writing of this Strategic Research and Innovation Agenda, work is ongoing on the development of the KPI framework with measurable expected outcomes at specific timepoints. Upon completion, the KPI framework will be adopted by the IHI Governing Board and published, becoming a formal document of the IHI JU. Adoption of the KPI framework by the IHI Governing Board is expected by mid-2022.

Thematic focus

The Innovative Health Initiative has been conceived to encompass disease areas focussing on unmet public health needs. The Partnership will cover the different stages in the healthcare pathway at which it intends to intervene, including prevention, detection, diagnostics, treatment, and disease management [5].

To identify focused areas for the Partnership's activities, three criteria will be considered:

(1)   the high burden of the disease for patients and/or society due to its severity and/or the number of people affected by it;

(2)   the high economic impact of the disease for patients and society;

(3)   the transformational nature of the potential results on innovation processes where projects are not focussed on individual disease (e.g. health data analytics).

Considering the diversity of EU Member States and regions, IHI will strive to ensure that its activities will reflect the varying needs and specificities of end-users in various geographical areas. IHI will also strive to pursue the aims of Directive 2010/63/EU [6] on the protection of animals used for scientific purposes and, in particular, the principle of the Three Rs to replace, reduce and refine the use of animals.

Synergies with other initiatives

In the case of R&I areas and activities that potentially fall under the scope of both IHI and several other EU-funded initiatives, including the Health Emergency Preparedness and Response Authority (HERA) activities, calls will be launched under the initiative with the most relevant scope, composition and overall goal for the specific topic. Only when duly justified (e.g. pandemic outbreak), and in cases where specific complementarities between initiatives are needed, multiple initiatives can launch calls in the same thematic areas.

IHI will interact with other health-oriented initiatives, initially with partnerships to be created in Cluster 1 of Horizon Europe. Annex II lists other partnerships relevant to IHI with which synergies will be encouraged. Interactions with the planned public-public European Partnership on Transforming Health and Care Systems (THCS) will be of particular importance as it may provide input for identification of scientific priorities, notably regarding unmet public health needs. Solutions proposed in the context of IHI may enable organisational innovations developed in the public-public THCS partnership. Organisational innovations or processes are not in scope of IHI since such innovations are solely the responsibility of healthcare authorities/organisations [7].

The Innovative Health Initiative will complement the actions of the EU4Health Programme wherever relevant, and those of the Digital Europe Programme that will deploy digital capacities and infrastructure related to the health area.

---

[5]   One of the inputs considered is the WHO "Health 2020: a European policy framework" report https://www.euro.who.int/__data/assets/pdf_file/0011/199532/Health2020-Long.pdf

[6]   https://eur-lex.europa.eu/eli/dir/2010/63/2019-06-26

[7]   The actual deployment of products or solutions in healthcare settings remain in the remit of individual healthcare organisations and in the national competence of Member States according to Art. 168 TFEU.

Horizon Europe has introduced the concept of missions, with cancer being one of the five mission areas that will use the full spectrum of European R&I instruments and policies to reach targets. The IHI will play an important role in supporting the development of innovations to prevent, faster diagnose and treat cancer and thus significantly contribute to Europe's Beating Cancer Plan [8] and the cancer mission [9]. The Plan will address cancer in a holistic way through four pillars: (1) prevention; (2) early detection; (3) diagnosis and treatment; and (4) quality of life of cancer patients and survivors.

Furthermore, the proposed initiative may foster the concept of 'Smart Health', an area that has been identified as one of the 'strategic value chains' [10] by a forum of industrial experts [11], with potential to drive EU's industrial competitiveness and promote technological sovereignty. Value chains are defined as a set of interdependent economic activities that add value around a product, process or service, involving a group of interlinked economic actors that operate across sectors and borders. The proposed initiative unites these features and has all the elements required to be considered strategic, i.e. revealing systemic importance and making a clear contribution to growth, jobs and competitiveness [12].

The value of IHI to serve as a precursor in this context has been further strengthened by the recently published industrial strategy [13]. It will demonstrate its full potential when delivering innovative health technologies that integrate digital components.

Finally, building on the relevant activities of its predecessor [14], the Innovative Health Initiative may contribute to providing health data under the European Health Data Space (EHDS) by promoting the FAIR principles (supporting discovery through good data management) and implementing EHDS policies, standards as well as semantic and technical framework. The EHDS is one of the sector-specific European Data Spaces under the European strategy for data, whose creation has been prioritised by the European Commission for the years 2019-2025 [15]. The European Health Data Space will promote the cross-border exchange and access to different types of health data to support both the primary use (i.e. healthcare delivery) and the secondary use of the health data (e.g. health research and policy making).

---

[8] https://ec.europa.eu/health/non_communicable_diseases/cancer_en and https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12154-Europe-s-Beating-Cancer-Plan

[9] https://ec.europa.eu/info/horizon-europe/missions-horizon-europe/cancer_en

[10] European Commission (2019), Strengthening strategic value chains for a future-ready EU industry. Report and annex available at: https://ec.europa.eu/docsroom/documents/37824; factsheet available at: https://ec.europa.eu/docsroom/documents/37825

[11] Strategic Forum for Important Projects of Common European Interest: https://ec.europa.eu/docsroom/documents/37824

[12] In the European political context, strategic value chains are characterised by: i) technological innovativeness; ii) economic and market potential; iii) societal and political importance for Europe; supporting Strategic Value Chains is a political priority at the interface of a number of other EU policies – R&I, industrial and the Green Deal.

[13] European Commission (2020), A new industrial strategy for Europe. https://ec.europa.eu/info/sites/info/files/communication-eu-industrial-strategy-march-2020_en.pdf

[14] e.g. the EHDEN project which has built a federated data network for allowing access to the data of 100 million EU citizens European Health Data and Evidence Network: https://www.imi.europa.eu/projects-results/project-factsheets/ehden

[15] European Health Data Space: https://ec.europa.eu/health/ehealth/dataspace_en

Specific Objectives of the Innovative Health Initiative

The IHI JU aims to achieve the following **Specific Objectives**:

1. contribute towards a better understanding of the determinants of health and priority disease areas;

2. integrate fragmented health research and innovation efforts bringing together health industry sectors and other stakeholders, focussing 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;

3. demonstrate the feasibility of people-centred, integrated healthcare solutions;

4. exploit the full potential of digitalisation and data exchange in healthcare;

5. enable the development of new and improved evaluation methodologies and models for a comprehensive assessment of the added value of innovative and integrated healthcare solutions.

IHI will launch calls for proposals and select projects (actions) that contribute to reaching one or more of these objectives [16].

---

[16] The progress towards achieving the specific objectives will be measured by a monitoring framework that is being developed in parallel (see Annex I for overview of all objectives).

SPECIFIC OBJECTIVE 1:

Contribute towards a better understanding of the determinants of health and priority disease areas

CHALLENGE:

For many health conditions, we lack full understanding of the underlying mechanisms, including the predisposition to disease, how environmental and genetic factors affect the occurrence and course of the diseases, what affects treatment success, etc. Consequently, it is difficult to develop adequate prevention strategies, accurate and timely diagnostics, and targeted therapeutic interventions. In order to develop innovative interventions ranging from health promotion to treatment, a better knowledge and understanding of the biological mechanisms is paramount. By elucidating the mechanisms of diseases and factors contributing to health status, IHI can provide better targets and approaches to develop new and more precise personalised health innovations for prevention, diagnosis and therapy, as well as facilitating good health while aging.

SCOPE:

The Innovative Health Initiative will cover the identification of new mechanisms underlying health status and disease development, biomarker identification and validation as well as elucidating potential new mechanisms for therapeutic actions, including innovative methods of data exploitation. The scope will also cover standardisation activities to facilitate the development of new health technologies, better identify individuals with disease predisposition, predict and monitor disease progression and assess the efficacy of targeted treatments.

In the specific context of IHI as a cross-sectoral partnership, more efficient use of various research tools or paradigms offered by emerging industry sectors (e.g. innovative imaging methods, robotics or artificial intelligence) may bring a new insight to understanding of health and disease. Using the services from European Research Infrastructures [17] for digitalised research (with reproducible workflows, data management and analysis, complex modelling and *in silico* simulation) could be beneficial.

POTENTIAL OUTPUTS ([18]):

- Increased understanding of health and disease mechanisms at a molecular level.

- Newly identified and validated biomarkers for disease interception, diagnosis, progression and treatment monitoring tested in real-world settings.

- Identification of common environmental factors, including social, with understanding of their impact on molecular mechanisms.

- Novel tools or hypotheses for new treatments tested preclinically and/or in early-stage clinical or *in silico* trials.

- Novel methods and tools to identify pre-symptomatic individuals.

- Validated protocols, diagnostic and prognostic tools (including those based on wearable devices).

---

[17] The Strategy Report on Research Infrastructures Part 3 describes – through dedicated cards – each ESFRI Project and each ESFRI Landmark. A short description of the RI is given as well as updated information on the legal status, the timeline for construction/operation, and the estimated costs. https://roadmap2021.esfri.eu/media/1252/rm21-part-3.pdf

[18] Output: immediate use or uptake of R&I results: e.g. results of productive interactions between producers and users of R&I (short and medium term)

- Validated *ex-vivo* and/or *in-vivo* solutions for patient monitoring during and after treatment, including those based on artificial intelligence approaches, database exploitation, computational modelling, and innovative sensing approaches.

- Improved understanding of host-pathogen (including microbiota) interactions if applicable.

- Tools to improve tracking of, and preparedness for, infectious disease outbreaks.

- Predictive models for the development of improved vaccines, taking into consideration the needs of specific populations like the elderly or children.

EXPECTED IMPACTS ([19]):

- Patients benefit from preventive treatment or early disease intervention before onset of symptoms.

- Prevention and early diagnosis of disease combined with better understanding of the mechanisms involved, leading to the development of more cost-effective strategies.

- Patients benefitting from improved healthcare through regular monitoring of critical parameters using validated tools.

- Development of new vaccine strategies targeted to specific sub-populations.

- Increased preparedness of EU healthcare systems for disease outbreaks.

([19]) Impact: wider benefit for society: e.g. social, economic and environmental impact (medium to long-term)

SPECIFIC OBJECTIVE 2:

Integrate fragmented health R&I efforts by bringing together health industry sectors and other stakeholders, focussing 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

CHALLENGE:

Rapid scientific and technical progress combined with the digital evolution lays the ground for the development of new types of products or services in the health domain that integrate diverse components (e.g. diagnostics, medicinal products, medical devices, wearables, treatment monitoring, digital solutions) in unprecedented ways. For example, a new treatment may be accompanied by a sensor and a mobile health solution that monitors adherence to the prescribed regime, and which may also collect data for monitoring treatment safety and efficacy. New possibilities for developing health interventions will benefit patients whilst offering new market opportunities to companies. However, the opportunities for developing integrated, interoperable healthcare solutions can only be fully harnessed if barriers to cross-sectoral collaboration and to collaboration with patients and healthcare professionals are overcome.

SCOPE:

Combinations of medicinal products, diagnostics, medical devices, wearables, telemedicine applications and complementary services are required to provide people-centred solutions along the healthcare pathway. Building on previous actions in this field, IHI will help break silos between basic research, medical disciplines and technological areas to provide the foundations for such people-centred care even before disease occurs, promoting health and well-being. Integration of *in vitro*, *in vivo* with data-driven diagnostics and prognostics should be a cornerstone of early and adapted treatment, including multimodal disease management approaches. This should consider the target population, including paediatric and geriatric patients. IHI may also help address regulatory challenges related to products that combine different technologies and services by offering a neutral platform for all interested stakeholders to exchange experiences and views on issues such as harmonisation of approaches to evidence generation across sectors.

This area will build on activities from Specific Objective 1, focussing on a better understanding of the causes of disease (aetiology), and its prevention and cure. It will contribute to activities of Specific Objective 4 where such an integrated approach will be key to allowing the collection of meaningful data, in particular on co-morbidities.

Activities will also address innovations and outcomes within the context of the European Green Deal, so that advances are part of Europe's sustainability goals, supporting commercial sustainability transition and reducing the overall environmental impact of healthcare.

POTENTIAL OUTPUTS:

- Methodologies and standards for the combination of technologies into integrated healthcare solutions to address pathologies or health impairments for an individual patient.

- Improved medical imaging and image analysis tools to facilitate diagnosis and treatment choice.

- Novel methods and tools to improve the design, the conduct and the analysis of clinical trials/investigations of innovative health technologies and their combinations.

- Novel methods and tools to improve post-marketing surveillance of innovative health technologies and their combinations.

- Novel methods and tools including observational and interventional clinical study design as well as analysis methods to evaluate the safety and clinical benefit of integrated healthcare solutions along the healthcare pathway.

- Development of interoperable solutions to detect variations in patient status in a home care environment.

- Innovations in manufacturing, exploring new decentralised, automated or semi-automated technologies or processes such as 3D-(bio)printing and mRNA platforms.

- Recognised contribution towards the European Green Deal for healthcare systems and improved competitive position within sustainable technologies and products.

EXPECTED IMPACTS:

- 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 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 (including health promotion and disease prevention) responding to patients' specific needs and leading to improved health outcomes and patient well-being.

- Patients and industry benefit from innovative manufacturing processes such as 3D printing, on-demand small-scale GMP synthesis, on-site portable production systems etc.

- Green transition enabled across all aspects of healthcare, both in the delivery of healthcare to patients, and in the technologies and products that emerge from competitive European industry.

SPECIFIC OBJECTIVE 3:

Demonstrate the feasibility of people-centred, integrated healthcare solutions

CHALLENGE:

Integrated healthcare solutions i.e., innovative solutions integrating various technologies, coupled with complementary tools and services, can offer breakthroughs in tackling health issues that are not currently effectively tackled. Integrating technologies across the healthcare pathway should be centred on people's needs and preferences. The importance of people-centricity, defined as placing people (including patients) at the heart of the healthcare system, is widely acknowledged. People-centricity is a condition for technological innovations to be taken up by individuals and healthcare systems across Europe, thereby addressing the problem of slow and insufficient knowledge translation.

Healthcare actors such as patients and civil society, healthcare professionals, healthcare providers, regulators, health technology assessment bodies and payers should take part in the design and development of new and/or integrated health solutions including via social innovation. Furthermore, people expect to play a stronger role in their own care and in the design of health products and services, from the research planning stage through to execution. Whilst scientific and technical evolution is rapid and provides many new opportunities, the integration of resulting technologies must be fostered within an environment that ensures the quality and the safety of the innovations, respecting ethical principles and complying with relevant legislation.

SCOPE:

The "one size fits all" model of some health products or approaches does not sufficiently cover individual characteristics of patients, e.g., age, gender, biological fingerprint and lifestyle choices, whilst personalised healthcare should constitute the core of the healthcare provision in the future (from prevention to outpatient recovery and aftercare) based on demonstrated safety, effectiveness and cost-effectiveness. IHI projects will investigate which solutions should be provided to people and at what time, thus avoiding unnecessary interventions and related costs, in addition to offering intervention as early as necessary, carefully weighing the risks versus the benefits.

The aim of IHI will be to lay the grounds for the development of integrated healthcare solutions, combining different technological areas and taking into account the needs of patients and citizens. Technological solutions can converge in novel ways (as addressed by Specific Objective 2) and this convergence should offer patient benefit while respecting the principles of safety, effectiveness, cost-effectiveness and privacy protection.

IHI will therefore engage citizens and patients in the development of integrated healthcare solutions to a) facilitate patient contribution to R&I activities, b) support shared decision-making with healthcare professionals, and c) enable self-management of disease and health, *de facto* engaging in social innovation. This implies, amongst others, the development of harmonised patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs), as well as the development of methods to elicit people's preferences and digital tools to enable patient involvement. Development of people-centred integrated care solutions will also require leveraging real-world evidence from multiple sources (thereby linking with the activities of Specific Objective 4).

POTENTIAL OUTPUTS:

- Understanding the prerequisites for successful EU-wide deployment of integrated solutions proposed by various technology sectors.

- Demonstration of feasibility from development of people-centred, integrated health-care solutions.

- Tools to facilitate patient engagement in R&I activities including in clinical trials.

- Validated PROMs and PREMs adapted to integrated healthcare solutions, in addition to alternative ways to improve user compliance/adherence.

- Methods for integration of PROMs and PREMs and more broadly people-generated information into the regulatory and health technology assessment processes as well as in the evaluation of healthcare delivery.

- Methodological approaches to elicit and integrate patient preferences into the development process of integrated healthcare solutions, from needs identification to implementation.

- Tools to enable/facilitate communication and interactions between patients, healthcare professionals and informal carers.

- Tools to enable/facilitate proactive health management for patients and provide real world evidence to healthcare professionals and informal carers.

- Tools to implement educational and accompanying programmes for patients and citizens, in particular regarding their role and contribution to health promotion and disease prevention.

- Tools to implement health literacy education programmes – including digital health literacy – for patients, healthcare professionals and informal carers.

- Better understanding of the factors affecting successful introduction of integrated healthcare solutions using digital technologies (anticipated value to users, factors affecting people engagement in addition to impacts on roles and responsibilities).

- Generation of evidence on, and quantification of, the benefit of integrated healthcare solutions using digital technologies to support people-centred care across Europe.

- Better understanding of the role of non-medical interventions and lifestyle change on prevention and disease management, and the added value of a digital companion.

EXPECTED IMPACTS:

- Raised awareness among citizens and patients on their own role in managing their health.

- Improved patient adherence to prevention programmes and medical interventions.

- People, including vulnerable populations (e.g., elderly and children as well as their carers and/or representatives) who are better able to make informed decisions with their healthcare professionals about prevention, treatment interventions and disease management.

- Increased frequency and quality of cooperation between patients, citizens and industrial stakeholders in the development of healthcare solutions, in particular integrated care solutions.

- Patients benefit from prevention and treatment better adapted to their needs through improved diagnostic and monitoring.

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

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

- Facilitated introduction of innovative solutions for improved home care of patients.

- Healthcare solutions assessed according to criteria that matter to patients and citizens (in particular PROMs and PREMs) contributing to achieving people-centred healthcare.

SPECIFIC OBJECTIVE 4:

Exploit the full potential of digitalisation and data exchange in healthcare

CHALLENGE:

Technological developments have made it possible to collect health data at much larger scale than was possible previously, e.g., from electronic health records, registries, biobanks, cohorts, claims databases, administrative data as well as data generated from wearable and portable sensory devices. The volume of data generated is also growing at very high pace – the overall data volume of connected devices and Internet of Things (IoT) is expected to grow over 480% between 2021 and 2025 [20]. As a consequence, the development of new products and services that rely on data-driven technologies, as well as the regulatory processes, are rapidly evolving.

The potential of real-world data/big data exploitation for public health research and innovation remains largely untapped. Currently, data in many countries are hard to gather, and demonstrate limited interoperability. Even when available, data and databases may exhibit variable quality, lack of standardisation and poor interconnectivity. Finally, training skills to handle, analyse and interpret the data are necessary. The EU offers a strengthened framework on data protection, but uncertainties remain, e.g., on the secondary use of health data and their pseudonymisation/anonymization, which creates an additional layer of complexity. Furthermore, security, explainability for users and ethical considerations should be ensured when developing new data analytics tools, including the use of artificial intelligence [21].

SCOPE:

The Partnership will aim at strengthening selected promising ongoing developments to harness opportunities of big data in healthcare. These include EU-wide initiatives in the area of health data standardisation (e.g., Electronic Health Record Exchange Format [22] uptake) and in the field of data-related regulatory science (e.g., HMA-EMA Joint Big Data Taskforce [23] and Joint Action on European Health Data Space (TEHDAS)).

IHI will support the generation, pooling, integration and sharing of high-quality, harmonised, interoperable data (either existing or generated *de novo*), as well as the use of advanced analytical tools (including Artificial Intelligence, modelling and simulation or digital twin approaches). This will be undertaken in a federated manner to facilitate R&I, promote collaboration among stakeholders, and better promote healthcare processes and care flows. It will also support the development of better assistance systems for healthcare professionals to facilitate timely decision-making during disease course, thereby improving patient outcomes. Artificial Intelligence and other advanced computational modelling can become an accompanying tool for physicians but cannot replace (the essential human component of healthcare, therefore the participation of patients (or their representatives) and healthcare professionals is key in the design of related studies. Exploring the use of advanced analytics, using advanced services from European Research Infrastructures, or other high-performance computing (HPC) capacities for digital-

---

[20] https://www.statista.com/statistics/1017863/worldwide-iot-connected-devices-data-size

[21] https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai

[22] Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format

[23] HMA/EMA Big Data Steering Group https://www.ema.europa.eu/en/about-us/how-we-work/big-data#hma/ema-big-data-steering-group-section

ised research could be beneficial, in particular for either big research data or more scarce data spread over clinical centres in Europe, e.g., for rare diseases.

POTENTIAL OUTPUTS:

- Contribution to developing data standards for healthcare, leveraging the experience from other data-related initiatives and data from repositories supporting clinical development of products and solutions.

- Contribution and access to common standards for interconnectivity and interoperability of databanks / registries of medical devices, wearable devices, and *in-vitro* diagnostics.

- Access to shared repositories of preclinical and clinical data, patients' real-world data, from pharmaceutical companies, medical technologies companies, digital health solution providers, and academia, compliant with GDPR.

- Demonstration of the feasibility of using various health data sources in a federated manner and interoperable with EHDS for the subsequent testing, deployment and use of artificial intelligence-based applications.

- Development of tools, technologies and methods for state-of-the-art data exploitation, respecting FAIR principles.

- Development of methods and case studies to assess performance of self-learning algorithms (e.g., against reference standards/ground truth).

- Training programmes organised on the use of new health IT tools and approaches for healthcare professionals.

- Development and piloting of methodologies and tools in cooperation with downstream decision-makers (e.g., regulators, HTA bodies, payers) making full use of real-world data from various sources and multiple stakeholders, both public and pri-

vate. These methodologies will in particular aim at identifying patterns and signals to improve clinical performance, safety and efficacy/effectiveness of medical products and services used in combination.

- Development of novel methodologies in cooperation with data permit and artificial intelligence authorities for patient stratification using analytics or biomedical models based on artificial intelligence, taking into account data, context and population information.

EXPECTED IMPACTS:

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

- Improved insight into the real-life behaviour and challenges of patients with complex, chronic diseases and co-morbidities thanks to m-health and e-health technologies.

- Advanced analytics/artificial intelligence supporting health R&I, resulting in a) clinical decision support for increased accuracy of diagnosis and efficacy of treatment, b) shorter times to market, c) wider availability of personalised health interventions to end-users, d) better evidence of the added value from new digital health and artificial intelligence tools, including reduced risk of bias due to improved methodologies.

SPECIFIC OBJECTIVE 5:

Enable the development of new and improved methodologies and models for a comprehensive assessment of the added value of innovative and integrated healthcare solutions

CHALLENGE:

Various initiatives (^{24}) have already provided useful tools and methods to assess the added value of health interventions, however emerging and converging technologies (^{25}) pose additional methodological challenges, partly because technology categories converge in ways that alter the delivery of healthcare (^{26}). In addition, a more integrated and people-centred approach would require assessment of contributions from individual technologies into the combined effect of the various health interventions delivered throughout the healthcare continuum. This raises methodological challenges such as (but not limited to) the development and consistent use of outcome measures relevant to patients. In addition, implementation of technological innovations in healthcare systems should ensure that innovation responds to people and healthcare system needs. Furthermore, effective, and cost-effective implementation may require the development of appropriate ancillary services and tools adapted to specific settings.

SCOPE:

To address the above-described challenges, IHI will aim to develop methods and tools:

- to contribute to advancing assessment of the value of emerging and converging health technologies;

- to assess the combined and specific effect on target population of individual health technologies applied throughout the healthcare continuum;

- to improve implementation of technological innovations in healthcare systems by providing a better understanding of the factors that would affect their successful introduction, and by anticipating the need for ancillary services and tools to be integrated within a given healthcare setting;

- to assess the added value of those integrated solutions (technological innovation and ancillary services) and their impact on the implementation process.

Whilst intended for use in informing decisions at different levels of the healthcare systems, those methods and tools will be based on common elements, in particular:

- integration of the perspectives of stakeholders (patients, carers, healthcare providers, healthcare professionals, industry, HTA bodies, regulators, policy makers and payers);

(^{24}) E.g., EUnetHTA Joint Action 3, EU-funded research projects (e.g. AdHopHTA, Advance-HTA, MedTechHTA, Integrate-HTA, COMED, IMPACT-HTA, PECUNIA, HTx) incl. IMI projects (e.g. GetReal and GetReal Initiative, Roadmap, Harmony, BigData@Heart, PIONEER, EHDEN), HTAi

(^{25}) Such as combinations of drugs and devices, nanotechnology-enabled products, medical devices employing digital communication tools, health interventions partially relying on robotics, Artificial Intelligence or software programs.

(^{26}) For example, medical devices are increasingly coupled with digital communication tools with the aim of improving the coordination of care and quality of care delivery which should ultimately translate into better outcomes for patients. Cost-effectiveness of such interventions is complex to assess due to the various and interacting components to be considered.

- integration of a societal perspective to capture the spillover effects including indirect costs of health interventions within and beyond the healthcare sector;

- integration of real-world evidence in value assessment.

IHI will elicit from the different stakeholders value dimensions (such as safety, effectiveness, cost-effectiveness, burden of disease, spillover effect, patient convenience, ethical/equity considerations, etc.). To assess those value dimensions, IHI will identify relevant outcomes along with outcome measures and the time horizon over which value is assessed and will develop appropriate tools and methods for data collection and data analysis. Integration of real-world evidence including on healthy populations will be key to assessing the value of the various healthcare interventions referred to in this Specific Objective (emerging and converging technologies, sequences of health interventions, integrated solutions). Development and use of PROMs and PREMs (in line with Specific Objective 3) will also be central to the value assessment of those healthcare solutions.

In addition, by providing an exchange platform for all stakeholders (in particular the industrial sectors, decision-makers, regulatory/competent authorities, national or regional bodies responsible for scientific evaluation of health technologies and patients), the partnership will support the development of harmonised approaches for evidence generation for innovative products combining different types of technologies.
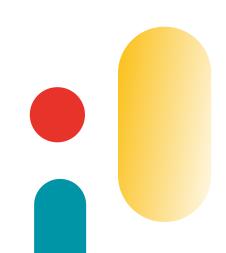
POTENTIAL OUTPUTS:

- Improved methods to transparently elicit stakeholder preferences regarding the various value dimensions and evaluation criteria.

- New and improved methodologies, tools, and recommendations for evidence generation throughout the evaluation pathway to inform those value criteria. This will include the collection of real-world data from various sources and development of analytical methods for their integration.

- New or improved methodologies and tools to assess the added value of emerging and converging technologies, sequences of health interventions and integrated solutions, to determine their long-term effects on costs and outcomes for patients, health systems (including healthcare providers and healthcare professionals) and societies.

- Evidence-based strategies to improve the successful implementation of innovative technologies in healthcare settings as well as methods and tools to assess the effectiveness and cost-effectiveness of those strategies.

EXPECTED IMPACTS:

- Seamless and successful implementation in healthcare settings of cross-sectoral innovations, integrated products and services delivering proven benefits to patients, healthcare systems and society as a whole.

- Patients have improved access to innovations that meet their needs and those of the healthcare systems.

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

- Faster entry to the market of cost-effective innovative solutions developed by industry, which could translate to a positive effect on their R&I investments.

Conclusions

When it comes to the health of its citizens, Europe is facing a unique moment. The continent provides some of the best healthcare in the world; it is a leader both in vaccine and drug discovery, in medical technology (medical devices, *in vitro* diagnostics) and in recent years, also in digital healthcare solutions. However, the COVID-19 pandemic has shown the fragility of the system. Today's fragmented ecosystem, confronted with the increasing complexity of healthcare innovation, makes it harder to sustain this leadership position. The time has come to use the innovations both in biology/medicine and in digital technology, and to reap their benefits along the entire healthcare spectrum. This is one way to position Europe at the forefront of implementation of the Strategic Developmental Goals (SDGs) from the United Nations.

This proposed SRIA aims to secure Europe's future competitiveness in a world where technologies are changing rapidly and where the design of tangible solutions needs input from all stakeholders in the value chain. Europe R&I has a long and renowned tradition of collaborative research, which provides a unique set of competencies and skills along the entire healthcare value chain. IHI offers a unique opportunity by driving multi-sector collaboration to accelerate the development of citizen-centred healthcare innovations in areas of unmet public health need.

The partnership will advance science and lay the groundwork for developing innovative health solutions by sharing expertise, resources and knowledge among the public sector and authorities, academia, and industrial actors.

The partnership will help strengthen the competitiveness of Europe's health industry, a cornerstone of its knowledge-based economy and a tool that supports strategic autonomy, introducing new business models and ways of working and reducing investment risk for the development of new products and services. It can shorten the time-to-market of innovative products and services and, directly and indirectly, create highly skilled jobs, both in academia and industry. Its contribution to improving the health of European citizens will also yield economic gains on multiple levels.

The Partnership is likely to contribute to improved health outcomes for European citizens, expressed as more life-years in good health and more years of independent life, a lower burden of disease, improved patient understanding and experience of healthcare, better diagnostics and more efficient therapies leading to personalised medicine. It is expected to constitute an incentive for industry to invest in unmet public health needs, such as cancer and mental disorders and neuro-degenerative diseases. The Partnership is expected to contribute to citizen and patient buy-in of healthcare solutions thanks to their active engagement in co-design, co-development, and testing via social innovation. Moreover, the partnership could contribute to the sustainability of healthcare systems and make innovative health interventions more accessible.

All citizens will benefit from new disease prevention methods, including new vaccines that might be developed as a result of IHI projects. Carers and healthcare professionals will benefit from integrated pathways allowing delivery of streamlined care that addresses their patients' issues. Companies will gain access to innovative solutions and products from cross-sectoral collaboration; technology development will be de-risked, and probability of success will be improved. Academics and SMEs will also be able to collaborate more easily. Overall, the sustainability and resilience of the whole health ecosystem, on which all these actors depend, will be improved.

Annex I: IHI objectives

The IHI JU aims to reach the following **general objectives** by 2030:

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 healthcare products or services, with demonstrated suitability for uptake by healthcare systems. The related projects should address the prevention, diagnosis, treatment and/or management of diseases affecting the EU population, including by 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 IHI JU aims to achieve the following **specific objectives**:

1. contribute towards a better understanding of the determinants of health and priority disease areas;

2. integrate fragmented health research and innovation by efforts bringing together health industry sectors and other stakeholders, focussing 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;

3. demonstrate the feasibility of people-centred, integrated healthcare solutions;

4. exploit the full potential of digitalisation and data exchange in healthcare;

5. enable the development of new and improved evaluation methodologies and models for a comprehensive assessment of the added value of innovative and integrated healthcare solutions.
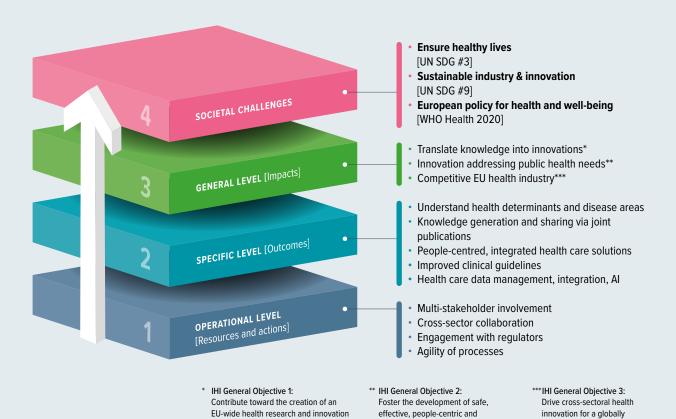
The following **operational objectives** will be pursued:

1. improve skills for cross-sectoral health innovation;

2. increase the involvement of patients and citizens in the generation and implementation of health innovations in Europe;

3. create a platform for health R&I collaboration as a safe pre-competitive space for brokering knowledge exchange, sharing ideas and resources across the various actors in the healthcare pathway (e.g. academics, health industry sectors, regulators, health technology assessment bodies, healthcare professionals and providers, payers, patients, informal carers, and citizens);

4. deliver pilots and demonstration projects to test the implementability of tools, models, methodologies and other innovations generated by the initiative;

5. develop tools and mechanisms to enable better access, sharing and analysis of health-related data, e.g., ethical frameworks, common standards and protocols;

6. deliver cross-sectoral R&I projects for the development of integrated, people-centred solutions and progress the understanding of the determinants of health and disease;

7. implement a time-efficient generation of priorities.

IHI vision: contribute to societal challenges through …

4 SOCIETAL CHALLENGES
- **Ensure healthy lives** [UN SDG #3]
- **Sustainable industry & innovation** [UN SDG #9]
- **European policy for health and well-being** [WHO Health 2020]

3 GENERAL LEVEL [Impacts]
- Translate knowledge into innovations*
- Innovation addressing public health needs**
- Competitive EU health industry***

2 SPECIFIC LEVEL [Outcomes]
- Understand health determinants and disease areas
- Knowledge generation and sharing via joint publications
- People-centred, integrated health care solutions
- Improved clinical guidelines
- Health care data management, integration, AI

1 OPERATIONAL LEVEL [Resources and actions]
- Multi-stakeholder involvement
- Cross-sector collaboration
- Engagement with regulators
- Agility of processes

* IHI General Objective 1:
Contribute toward the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations

** IHI General Objective 2:
Foster the development of safe, effective, people-centric and cost-effective innovations that respond to strategic unmet public health needs

***IHI General Objective 3:
Drive cross-sectoral health innovation for a globally competitive European health industry

Annex II: Other candidate European Partnerships of potential relevance (^{27})

Name	Short description of the aim
Global Health EDCTP3	Increase global health security in sub-Saharan Africa and Europe by accelerating the clinical development of effective, safe, accessible, suitable and affordable health technologies as well as health system interventions for infectious diseases in partnership with Africa and international funders. Support implementation research and health systems research for the uptake of new, improved or existing medical interventions.
Partnership on Transforming Health and Care Systems	Pool a critical mass of European/national/regional scientific resources to research, develop and test organisational, service and policy innovations. The context-specific knowledge and evidence will inform health and care policies and facilitate uptake of innovations, as well as their scaling-up and transfer to other countries and regions.
Personalised Medicine	Align priority setting and fund research projects in the area of personalised medicine between EU Member States and regions, associated countries and international partner countries. Make recommendations for wider roll-out of personalised medicine approaches in healthcare.
Rare Diseases	Improve the integration, effectiveness, production and social impact of research on rare diseases through the development, demonstration and promotion of Europe/ world-wide production, sharing and exploitation of research and clinical data, materials, processes, knowledge and know-how.
One Health AMR	Bring together the many aspects of antimicrobial resistance (AMR) to overcome fragmentation of the AMR research landscape, and integrate the various different research fields (addressing human health, animal health, food safety and environment). Contribute to the EU One Health Action Plan against AMR that provides the framework within which action should be taken.

(^{27}) Final determination depends on the confirmation of the scope of the partnerships. See full list https://ec.europa.eu/info/re-search-and-innovation/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/european-partner-ships-horizon-europe_en

Name	Short description of the aim
European Research Area (ERA) for health research	Establish a flexible and more effective coordination between programme owners (typically ministries) and programme funders (typically funding agencies) of the numerous networks established in the European Research Area (ERA) for Health and Well-being. It would focus on establishing a strategic research and innovation agenda and joint funding strategy between major European funders, public and private, on translational health research and innovation. It will also design the joint funding for wide-scale investigator-initiated clinical studies with a high European public health value. The new ERA4Health Partnership will provide a coordinated effort to prioritise and identify areas with the most urgent needs for investigator-initiated clinical studies that can deliver/promote optimised standard of care based on robust and reliable clinical evidence for efficacy, safety and quality.
Joint Programming in Neurodegenerative Diseases (JPND)	Increase coordinated investment between participating countries (Europe and beyond) in research aimed at finding causes, developing cures, and identifying appropriate ways to care for those with neurodegenerative diseases. Enabling early diagnosis for early-targeted treatments is an additional key goal.
ERA-NET NEURON	Aligning national and regional funding programmes and building a basis for a European (and global) brain research area to support research into the brain and nervous system diseases, more particularly addressing mental disorders, neurological conditions (except neurodegeneration) and sensory disorders. This will pave the way for new or improved routes for diagnosis and therapy.
Partnership for the Assessment of Risk from Chemicals (PARC)	Bring together the European risk assessment and regulatory agencies, as well as their scientific networks, to implement a joint research and innovation agenda to ensure their capacity to deal with persistent or emerging challenges. Promote the uptake of new methods, tools, technologies and information in chemical hazard identification and risk assessment and, as part of this, sustain the development and use of human biomonitoring capacities in Europe.
Animal health: fighting infectious diseases	Bring sustainable and innovative solutions to tackle infectious animal diseases, including those transmitted between animals and humans (zoonoses) and to contribute to the fight against anti-microbial resistance, implementing the One Health concept. Support sustainable animal production, reduce trade barriers, and protect consumers.
Key Digital Technologies	Maintain the European Electronics Components and Systems industry at the technological forefront and contribute to boosting the EU's competitiveness, including that of its industries, by providing essential components and software as well as the related manufacturing infrastructure in Europe and national strategies.
High Performance Computing	Establish an integrated world-class supercomputing and data infrastructure and support a highly competitive and innovative high performace computing and big data ecosystem.

Name	Short description of the aim
Smart Networks and Services	Enable the infrastructure basis in terms of key technologies and deployment for Next-Generation Internet services used by citizens and for "smart" services required by vertical sectors such as transport, energy, manufacturing, health and media.
AI, data and robotics	Structure the European AI community, develop a strategic research and innovation agenda and federate efforts around a topic that holds great potential to benefit our society and economy.
Photonics	Speed up photonic innovations for a digital, green and healthy future in Europe, securing Europe's technological sovereignty, raising the competitiveness of Europe's economy and ensuring long-term job and prosperity creation.
EIT Health	Enable people in Europe to live longer, healthier lives by building and growing businesses to create products and services that progress healthcare in Europe, while strengthening the economy and the sustainability of healthcare systems.

Annex III: Glossary

BIG DATA refers to extremely large datasets which may be complex, multi-dimensional, unstructured and heterogeneous, which are accumulating rapidly and which may be analysed computationally to reveal patterns, trends, and associations. In general, big data sets require specialised methods to provide an answer within reliable constraints.

BIOBANKS are repositories that store biological samples for use in research.

BIOMARKERS are biological characteristics, which can be molecular, anatomic, physiologic, or biochemical. These characteristics can be measured and evaluated objectively. They act as indicators of a normal or a pathogenic biological process. They allow the assessment of the pharmacological response to a therapeutic intervention. A biomarker shows a specific physical trait or a measurable biologically-produced change in the body that is linked to a disease or a particular health condition. A biomarker may be used to assess or detect a specific disease as early as possible (diagnostic biomarker), the risk of developing a disease (susceptibility/risk biomarker), the evolution of a disease (prognostic biomarker) – but it can also predict response to a given treatment including potential toxicity (predictive biomarker).

COST-EFFECTIVE: Cost-effective health interventions are identified through Cost-Effectiveness Analyses (CEA). CEA estimate the costs and health outcomes of alternative interventions (be it promotional, preventative, curative, rehabilitation) that are then compared in terms of cost per unit of health gain. Health outcomes are typically life-years gained or quality-adjusted life years (QALYs) representing a weighted combination of mortality and morbidity effects. Cost-effective interventions are those that yield the greatest improvement in health for the least resources. CEA provides a method for prioritising the allocation of resources while maximising health gain. It should be noted that "cost-effective" and "cost-saving" are often mistakenly used interchangeably although they are distinct terms. If the benefits are sufficiently large compared to the costs, the intervention is "cost-effective" even if it does not save money.

DATA ANALYTICS refers to the discovery and communication of meaningful patterns in data, also in order to make sense of the 'big data'. Data analytics techniques analyse datasets to describe, predict, and improve performance.

Data security refers to the protection of personal data from unauthorised or unintentional loss, theft, access, use, modification, or disclosure.

DISEASE MANAGEMENT (PROGRAMME): Definitions of disease management (programmes) vary substantially. Common features are: 1) an

integrated approach to care/coordination of care among providers, including physicians, hospitals, laboratories and pharmacies; 2) patient education; and 3) monitoring/collecting patient outcomes data for early detection of potential complications.

eHEALTH INTEROPERABILITY means the ability of two or more eHealth systems to use and exchange both computer interpretable data and human-understandable information and knowledge.

ELECTRONIC HEALTH RECORD (EHR) refers to a record in digital format containing medical information about a patient. Such records may include a whole range of data in comprehensive or summary form, including demographics, medical history, medication and allergies, immunisation status, laboratory test results, radiology images, vital signs, personal statistics like age and weight and billing information.

HEALTHCARE PROVIDERS encompass 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 etc.

HEALTHCARE SOLUTION in this document refers to a medical product, ancillary service or tool used either alone or in combination in order to address a specific healthcare need, be it a medical need or an organisational need.

HEALTH TECHNOLOGY means a medicinal product, a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare.

HEALTH TECHNOLOGY ASSESSMENT (HTA) is an evidence-based multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective health policies that are patient focused and seek to achieve best value. HTA focuses specifically on the added value of a new health technology in comparison to the existing standard of care in the healthcare system. HTA is not only used to inform local/national pricing and reimbursement decisions but also to support the development of evidence-based clinical guidelines and public health recommendations.

HEALTH LITERACY refers to the knowledge, motivation and competencies in accessing, understanding, appraising and applying health-related information within healthcare, disease prevention and health promotion settings.

INTEGRATED CARE includes initiatives seeking to improve outcomes of care by overcoming issues of fragmentation through linkage or co-ordination of services of providers along the continuum of care.

IN-VITRO DIAGNOSTIC MEDICAL DEVICE means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:

● a physiological or pathological process or state;

● congenital physical or mental impairments;

● the predisposition to a medical condition or a disease;

● the safety and compatibility with potential recipients;

● predicting treatment response or reactions;

● defining or monitoring therapeutic measures.

MEDICAL DEVICE means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

● diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

● diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

● investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

● providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

MEDICINAL PRODUCT refers to a substance or combination of substances that is intended to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action.

MEDICAL IMAGING refers to the technique and process used to create images of the human body to reveal, diagnose, or examine a disease.

METHOD VALIDATION is the process used to confirm that the analytical procedure employed for a specific test is suitable for its intended use. Results from method validation can be used to judge the quality, reliability and consistency of analytical results. In particular, the following measurements will be performed: Selectivity/specificity, Precision (repeatability, reproducibility), Bias/Recovery, Working range, Ruggedness/robustness.

ORGANISATIONAL INNOVATION (also known as management innovation or administrative innovation) encompasses a wide range of processes, from changing professional practices and roles, to changing organisational structures and governance arrangements.

PAYERS in this document denote tax-funded national/regional payers and statutory/mandatory health insurance funds (social health insurance, SHI), National Health Services (NHS) and SHI ensuring publicly financed healthcare (the "benefits package"). In some Member States, additional products and services can be covered by voluntary complementary/supplementary private health insurance.

PEOPLE-CENTRED CARE refers to an approach to care that consciously adopts individuals', carers', families' and communities' perspectives and sees them as participants as well as beneficiaries of healthcare systems that are organised around their needs and preferences rather than individual diseases.

PATIENT SELF-MANAGEMENT refers to the systematic provision of education and supportive interventions by healthcare staff to increase patients' skills and confidence in managing their health problems, including regular assessment of progress and problems, goal setting, and problem-solving support.

PERSONALISED MEDICINE refers to a medical model using characterisation of individuals' phenotypes and genotypes (e.g., molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention. Personalised medicine relates to the broader concept of patient-centred care, which takes into account that, in general, healthcare systems need to better respond to patient needs.

PATIENT-REPORTED EXPERIENCE MEASURE (PREM) is a measurement of patients' perceptions of their experience of the process (rather than outcome) of care (e.g., satisfaction with information provided by healthcare professionals, or waiting time before the first appointment).

PATIENT-REPORTED OUTCOME (PRO) is any report of the status of a patient's health condition (e.g. quality of life, symptoms, treatment effects, functioning) elicited directly from the patient, without interpretation of the patient's response by a clinician or anyone else. The tools used to capture information about PROs are called Patient-Reported Outcome Measures (PROMs).

REAL-WORLD DATA are data regarding the effects of health interventions that are not collected in the context of conventional randomised controlled trials but prospectively and retrospectively from observations in routine clinical practice from many sources including patient registries, electronic medical records, and observational studies. Real world data include but are not limited to routinely collected data.

REAL-WORLD EVIDENCE refers to insight or knowledge derived from the analysis of real-world data, conducted to respond to a specific research question.

REGULATORS refers in this document to the different bodies involved in the processes regulating medical products (e.g., scientific assessment, production of scientific guidelines, scientific advice to manufacturers, granting/refusal/suspension of marketing authorisations, post-market surveillance, withdrawing/recalling of devices put on the market, authorisation and oversight of clinical trials). It includes the European Commission, National Competent Authorities (NCA), the Medical Device Coordination Group (MDCG), and the European Medicines Agency (EMA). Notified Bodies (NB), while designated to perform a regulatory function (verification of medical device/in-vitro diagnostics conformity), cannot be considered as regulators in the strict sense of this definition. However, the potential input and expertise of Notified Bodies may still be relevant for the design and implementation of the activities of the proposed initiative.

SOCIAL INNOVATION concerns the development of new products, methods, and services for and with society involving citizens, public authorities, business and industry, and academia—the "Quadruple Helix"—in their design, development, and implementation. Social innovation engages and empowers citizens, enhances the resilience of communities, increases the relevance, acceptance and uptake of innovation, and helps foster lasting changes in social practices, therefore acting as a system changer.

STANDARD refers to an agreed, repeatable way of doing something. It is a published document that contains a technical specification or other precise criteria designed to be used consistently as a rule, guideline, or definition.

UNMET PUBLIC HEALTH NEEDS are needs currently not addressed by the 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.

A VACCINE is a biological preparation that provides active acquired immunity to a particular disease.

VALUE IN HEALTHCARE is a multidimensional concept that the Expert Panel of effective ways in investing in Health (EXPH) describes as based on four pillars: personal value, technical value, allocative value and societal value [28]. Most common elements of existing frameworks to assess the value of health interventions include the following domains/dimensions: therapeutic benefit, safety, costs, innovation level, health problem (severity of the disease and medical need), organisational aspects, ethical aspects, social and legal aspects. Those various elements need to be evidence-based and combined using an appropriate approach (e.g. cost-effectiveness analysis,

[28] https://op.europa.eu/en/publication-detail/-/publication/d7087e5e-ac2b-11e9-9d01-01aa75ed71a1

multi-criteria decision analysis) in order to inform decision-making on the reimbursement, pricing, adoption, and implementation of health interventions. The report also addresses value in healthcare from the perspectives of all actors from patients and professionals/providers, to industry and Member State authorities, taking into account the goals and means to achieve these goals by each stakeholder.

COCIR: European Coordination Committee of the Radiological, Electromedical and Healthcare IT industry, www.cocir.org/

EFPIA: European Federation of Pharmaceutical Industries and Associations, www.efpia.eu/

EUROPABIO: European Associations for Bioindustries, www.europabio.org/

MEDTECH EUROPE: European trade association representing the medical technology industries, from diagnosis to cure, www.medtecheurope.org/

VACCINES EUROPE: www.vaccineseurope.eu/

FIND OUT MORE ABOUT IHI

Visit our website: ihi.europa.eu
Follow us on Twitter: @IHIEurope
Follow us on LinkedIn: innovative-health-initiative
E-mail us: infodesk@ihi.europa.eu
Call us: +32 (0)2 221 81 81

FINDING INFORMATION ABOUT THE EU

Online
Information about the European Union in all the official languages of the EU is available on the Europa website at: https://europa.eu/european-union/index_en

EU publications
You can download or order free and priced EU publications at: https://op.europa.eu/en/publications. Multiple copies of free publications may be obtained by contacting Europe Direct or your local information centre (see https://europa.eu/european-union/contact_en).

EU law and related documents
For access to legal information from the EU, including all EU law since 1951 in all the official language versions, go to EUR-Lex at: http://eur-lex.europa.eu

Open data from the EU
The EU Open Data Portal (http://data.europa.eu/euodp/en) provides access to datasets from the EU. Data can be downloaded and reused for free, for both commercial and non-commercial purposes.

ihi.europa.eu
@IHIEurope

Publications Office
of the European Union