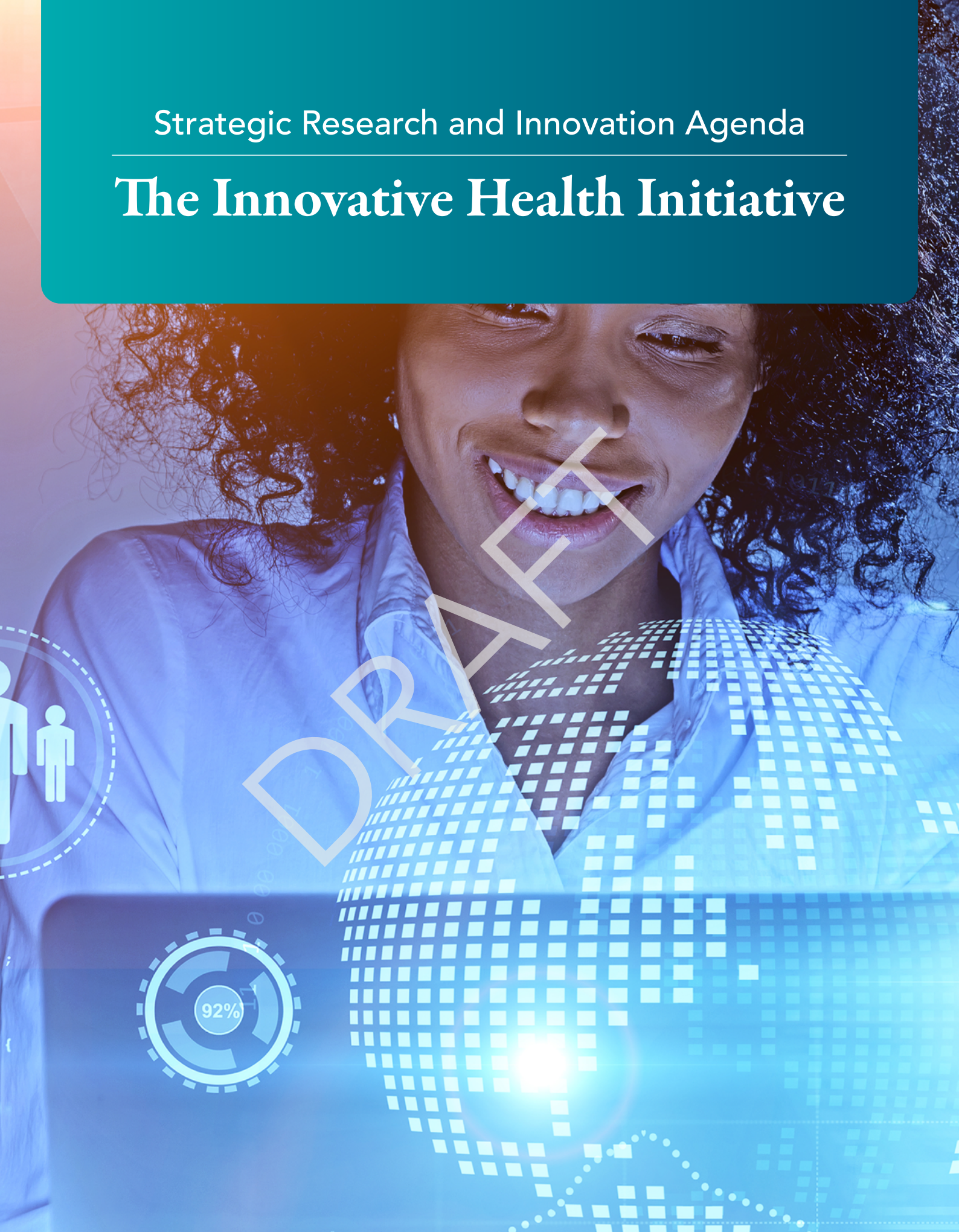
Strategic Research and Innovation Agenda

The Innovative Health Initiative



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The Innovative Health Initiative aims to enable the cross-sectoral integration of technologies, know-how, products, services and workflows for people-centred health care.
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 health care professionals. It will contribute to the sustainability and resilience of health care systems, to the competitiveness of health industries and to the EU technological strategic autonomy.

This draft document was prepared jointly by the prospective IHI JU member industry associations and the European Commission services. The Strategic Research and Innovation Agenda will reflect the final views of the European Commission once it becomes a formal document of IHI JU upon finalisation and adoption by its Governing Board. This document does not pre-empt the outcome of the formal decision-making process or the legislative procedure for the establishment of joint undertakings.

If you would like to receive further information about this initiative, please contact:
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Contents

Chapter 1

Vision of the Innovative Health Initiative

Health care in Europe faces multiple challenges

Europe has always strived to deliver high standards of health care. At the same time, health is a constant and major concern for many Europeans, as confirmed by Eurobarometer surveys[1]. The EU has an ageing population and a rising burden of related diseases, notably the non-communicable ones (for example cardiometabolic diseases, cancers, neurodegeneration, or musculoskeletal disorders). Most countries struggle with long-term expenditure and workforce planning in health care and the problem grows as the age pyramid changes. The health care expenditure in EU countries is steadily increasing and in 2017 it accounted for nearly 10% of EU Gross Domestic Product (GDP), most of which originating from public sector spending (7%)[2]. This challenges the long-term sustainability of EU health care systems, which are under increasing fiscal and organisational pressures.

The COVID-19 health crisis uncovered the challenges that European health care systems face in detecting, combatting and managing outbreaks of infectious diseases in a coordinated manner. At the same time, the relentless work of the research community that has led to 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 health care could be made by innovative health care interventions. However, they are notoriously complex to design and even more so to implement as they may stretch over the full spectrum of the health care pathway: from prevention through diagnosis and treatment, to disease management including long-term and palliative care. Innovation in health care is today based on the use of established and innovative technologies (including medicinal products, medical devices, blood-tissue-cell-based therapies, digital technologies including artificial intelligence, nanotechnologies, etc.) sometimes used in combination. Fostering the convergence of technologies will enable the development of cross-sectoral innovations more 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 health care 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, the still existing silos would have to be broken down across discovery science and translational research as well as between different academic research disciplines and industry sectors. This would ensure faster development of people-centred, safe, effective, cost-effective and affordable health solutions. To do so, it is crucial to involve all stakeholders including citizens in the co-design, co-development and

1 https://ec.europa.eu/commfrontoffice/publicopinionmobile/index.cfm/Survey/getSurveyDetail/surveKy/2180

2 https://ec.europa.eu/eurostat/statistics-explained/index.php/Healthcare_expenditure_statistics#Healthcare_expenditure

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 health care 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 the health care systems in Europe. This could partially be attributed to insufficient early consideration of societal and/or user needs. Therefore, patients and end-users in general need to be involved in all stages of research, from project design to implementation, to develop meaningful innovations.

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

New science and technologies have yet to gain traction

Medical science and practice is becoming increasingly interdisciplinary, integrating bioinformatics, biomechanics and biochemistry, chemistry, physics, mathematics, biology, micro-electronics and nanotechnologies, data as well as social and behavioural knowledge. Additionally, without leveraging the potential of Big Data, real world data and digital tools, a great opportunity might be missed as regards, for instance, our understanding of complex, multifactorial diseases as well as complex interdependencies between diseases in an aging society.
The causal factors of many diseases are still poorly understood; notably, the interplay between genetic and environmental factors. Deciphering their impact on disease onset and disease course, as well as on treatment success, remains a long-term desirable target in health care.

Although the recent development in EU digital health policy, such as the European Health Data Space initiative are making steps to address the current gaps, the potential of (big) data in terms of public health and health care 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.

While 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, as well as scientific and ethical considerations must be duly taken into account when developing data access and exchange protocols, FAIRification anonymization 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 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[3]. IHI also builds on the lessons learned from the health activities in the ECSEL JU. These activities mainly focus on the enabling electronics components and systems aspects. Moreover, there are several health-related activities pursued under the ECSEL JU, like e.g. the actions on the establishment of pilot production lines for smart medical devices and implants involving a range of MedTech actors, which are of high relevance for future activities under IHI.

IHI is not meant to be a direct continuation of IMI2 JU. Rather, it will have a broadened scope with new partners and stakeholders.

The proposed initiative reflects the importance of the full spectrum of health technologies, as well as the progress in convergence of health technology areas and a much more prominent role of digital technologies and data analytics in health research than it was the case 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" [4]. 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.

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 the foundations for the development of safer and more effective health care products or solutions that respond to unmet public health needs and that can be taken up by health care systems.

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 health care products or services, with demonstrated suitability for uptake by health care systems. The related projects should address the prevention, diagnosis, treatment and/or management of diseases affecting the EU population,

3 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.

4 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

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

The activities will consider the different innovation cycles of pharmaceutical and medical technology industries. While the 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 for 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 aiming at delivering products or services directly in health care 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 in the development of new health care interventions.
2. People-centric, rather than product- and pathology-centric, goals – the focus will be the patient and citizen's journey through health care with the help of most suitable health technologies and social innovations taking account of demographic trends.
3. Early engagement with public sector stakeholders for the definition of priorities should be ensured by setting up an Innovation Panel, involving relevant public and private stakeholders from the health care ecosystem. This will also ensure that IHI projects will better reflect the needs of health care systems, including cross-border scenarios.
4. The sustainability and impact of the projects will be increased by setting concrete performance and impact targets as part of the projects' design. This greater understanding of impact will bring more clarity on the follow-up and up-take (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, including 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.

Thematic focus

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

To select focused areas of the Partnership's activities, three criteria will be considered by the Innovation Panel and by the Governing Board:
(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 use for scientific purposes and, in particular, the principle of the Three Rs to replace, reduce and refine the use of animals.

5 One of the inputs considered is the Priority Medicines for Europe and the World Update Report, 2013: https://www.who.int/medicines/areas/priority_medicines/en/

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

Synergies with other initiatives

In case of R&I areas and activities potentially falling in scope of IHI and several other EU-funded initiatives, including the Health Emergency Preparedness and Response Authority (HERA) activities, calls will be launched only under the initiative having the most relevant scope, composition and overall goal for the specific topic. Only when duly justified (e.g. by pandemics 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 a series of other health-oriented initiatives, to start with other 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 could enable organisational innovations developed in the public-public THCS partnership. However, 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 health area.

Horizon Europe has introduced the novelty 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 their targets. The Innovative Health Initiative will play an important role in supporting the development of innovations to prevent, faster diagnose and treat cancer and thus significantly contribute to the 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 industrialexperts[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

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

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. R port 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/transparency/expert-groups-register/screen/expert-groups/consult?do=groupDetail.groupDetail&groupID=3583&NewSearch=1&NewSearch=1

all elements to be considered as "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 may 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 could 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 prioritized 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. health care delivery) and the secondary use of the health data (e.g. health research and policy making).

12 In the European political context, strategic value chains are characterised by: i) technological innovativ ness; 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.

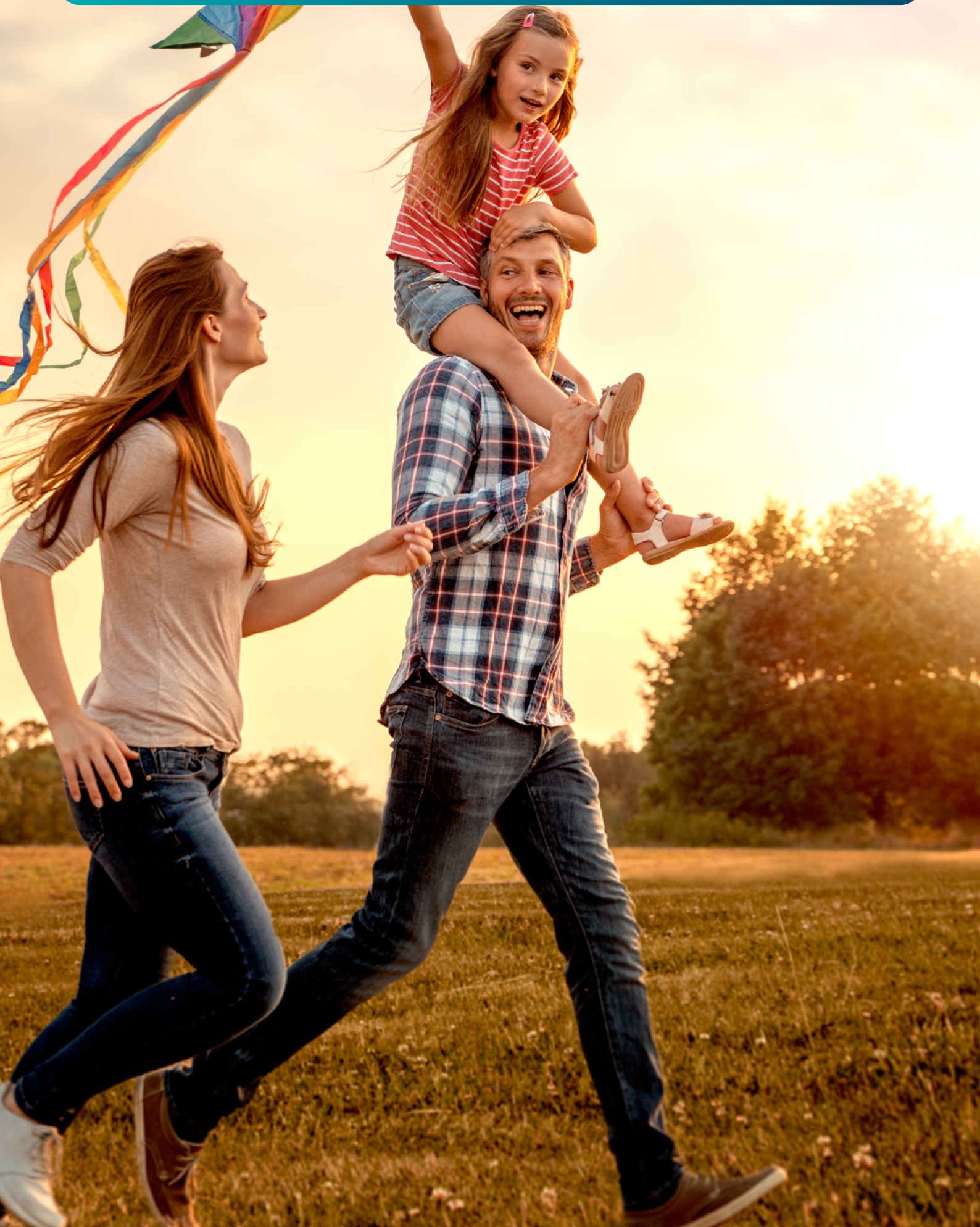
13 European Commission (2020), A new industrial strategy for Europe. https://ec.europa.eu/info/sites/info/files/communication-eu-industrial-strategy-march-2020_en.pdf

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

Chapter 2

Specific Objectives of the Innovative Health Initiative



Chapter 2
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 health care solutions;
4. exploit the full potential of digitalisation and data exchange in health care;
5. enable the development of new and improved evaluation methodologies and models for a comprehensive assessment of the added value of innovative and integrated health care 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. 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 facilitate staying in good health longer while aging.

Scope

The Innovative Health Initiative will cover the identification of new mechanisms underlying the health status and diseases development, biomarkers identification and validation as well as elucidating potential new mechanisms for therapeutic action, including innovative ways of data exploitation. The scope will also cover standardisation activities to facilitate the development of new health technologies, to better identify individuals with disease predisposition, to predict and monitor disease progression and to 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 new industry sectors (e.g. using innovative imaging methods or artificial intelligence) may bring a new angle to the understanding of health and disease. Using the services from European Research Infrastructures or EOSC-Life[17] for digitalized 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 molecular level.
- Newly identified and validated biomarkers for disease interception, diagnosis, progression and treatment monitoring tested in real-world settings.
- New tools or hypotheses for new treatments, tested in early stage clinical studies or in silico trials.
- New methods and tools to identify pre-symptomatic individuals.
- Validated protocols, diagnostic and prognostic tools (including those based on wearable devices).
- Validated ex-vivo and/or in-vivo solutions for patient monitoring during and after treatment, including those based on artificial intelligence approaches, databases exploitation, computational modelling and new sensing approaches.
- Improved understanding of host-pathogen (including microbiota) interactions, if applicable.

17 The EU-funded EOSC-Life project brings together 13 Life Science Research Infrastructures in ESFRI to create an open, digital and collaborative space for life science research in the European Open Science Cloud; https://www.eosc-life.eu/

18 Outputs: Results of R&I, e.g. new knowledge, advice, technologies, processes, data, methodologies.

- 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 intervention before onset of the disease
- Prevention and early diagnosis of disease, combined with better understanding of the mechanisms involved would lead to the development of more cost-effective strategies.
- Patients would benefit from better health care through regular monitoring of critical parameters using validated tools
- Development of new vaccine strategies targeted to specific sub-populations
- Increased preparedness of EU health care 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 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

The rapid scientific and technical progress and the digital evolution lays the ground for the development of new types of products or services in the health domain that integrate the different components (spanning 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 the adherence to the prescribed regime, and it may also collect data for monitoring the treatment safety and efficacy. The new possibilities for developing health interventions can benefit patients while offering new market opportunities to companies. However, the opportunities for developing integrated, interoperable health care solutions can only be fully harnessed if barriers to cross-sectoral collaboration are overcome.

Scope

Combinations of medicinal products, diagnostics, medical devices, wearables, telemedicine applications and complementary services are needed to provide people-centred solutions along the health care 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 and data driven diagnostics and prognostics should be a cornerstone of early and adapted treatment, including multimodal disease management approaches. IHI may also help address regulatory challenges related to products combining different technologies and services by offering a neutral platform for all interested stakeholders to exchange their experience 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 allow for the collection of meaningful data, in particular on co-morbidities.

The implementing activities should also consider innovations in manufacturing and in particular green manufacturing and lowering the overall environmental footprint in accordance with the European Green Deal.

Potential outputs

- Methodologies and standards for the combination of various technologies into integrated health care solutions to tackle 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 clinical study design and analysis methods to evaluate the safety and clinical benefit of integrated health care solutions along the health care 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

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 health care solutions that can seamlessly be introduced in health care 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 health care pathway (including health promotion and disease prevention) responding to patients' specific needs 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.

Specific Objective 3: Demonstrate the feasibility of people-centred, integrated health care solutions

Challenge

Integrated health care solutions i.e., innovative solutions integrating various technologies, coupled with complementary tools and services, may offer breakthroughs in tackling health issues that cannot be effectively tackled today. Integrating various technologies across the health care pathway should be centred on people needs and preferences. The importance of people-centricity, defined as placing people (including patients) at the heart of the health care system, is widely acknowledged. It is a condition for technological innovations to be taken up by individuals and health care systems across Europe, thereby addressing the problem of slow and insufficient knowledge translation. Therefore, health care actors such as patients and civil society, health care professionals, health care providers, regulators, health technology assessment bodies and payers should take part in the design and development of new 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, starting from the research planning and execution phase. While the scientific and technical evolution is rapid and provides many new opportunities, the integration of resulting technologies must be fostered in 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 certain health products or approaches does not sufficiently cover the individual characteristics of patients, e.g. age, gender, biological fingerprint and lifestyle choices, while personalised health care should constitute the core of the health care provision in the future (from prevention to outpatient recovery and aftercare) based on demonstrated safety, effectiveness and cost-effectiveness. The IHI projects will investigate what solutions should be provided to people and at what time, thus avoiding unnecessary interventions and related costs, as well as offering the 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 health care solutions, combining various technological areas while taking into account the needs of patients and citizens. Various technological solutions 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 health care solutions a) to facilitate patient contribution to R&I activities, b) to support shared decision-making with health care professionals, and c) to enable self-management of disease and health, de facto engaging in social innovation. This implies, among others, the development of harmonized 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. The developments of people-centred integrated care solutions would also require leveraging real-world evidence from various sources (thereby linking with the activities of Specific Objective 4).

Potential outputs

- Understanding the prerequisites for successful integration of solutions proposed by various technology sectors.
- Examples of demonstration of feasibility of developing 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 health care solutions, as well as alternative ways to improve user compliance/adherence.
- Methods for the integration of PROMs and PREMs and more generally people-generated information in the regulatory and health technology assessment processes as well as in the evaluation of health care delivery.
- Methodological approaches to elicit and integrate patients' preferences in the development process of integrated health care solutions from needs identification to implementation.
- Tools to enable/facilitate communication and interactions between patients, health care professionals and informal carers.
- Tools to enable/facilitate proactive health management for patients and provide real world evidence to health care professionals and informal carers.
- Tools to implement educational and accompanying programmes for patients and citizens, in particular on their role and contribution to the health promotion and disease prevention.
- Tools to implement health literacy education programmes – including digital health literacy – for patients, health care professionals and informal carers.
- Better understanding of the factors affecting successful introduction of integrated health care solutions using digital technologies (anticipated value to users, factors affecting people engagement as well as impacts on roles and responsibilities).
- Generation of evidence on – and quantification of - the benefit of integrated health care 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 of 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) better able to make informed decision with their health care professionals about prevention, treatment interventions and disease management.
- Increased frequency and quality of cooperation between patients, citizens and industrial stakeholders in the development of health care solutions, in particular integrated care solutions.
- Patients benefit from prevention and treatment better adapted to their needs through improved diagnostic and monitoring.
- Integrated health care 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.
- Health care solutions assessed according to criteria that matter to patients and citizens (in particular PROMs and PREMs) contributing to achieving people-centred health care.

Specific Objective 4: Exploit the full potential of digitalisation and data exchange in health care

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 data volume 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% from 2021 to 2025[20]. Therefore, the development of new products and services relying 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 are hard to gather and demonstrate limited interoperability. Even when available, data and databases may exhibit variable quality, lack of standardization 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 pseudonymization/anonymization, which creates an additional layer of complexity. Furthermore, security, explainability for the users and ethical considerations should be ensured when developing new data analytics tools, including the use of Artificial Intelligence.

Scope

The partnership will aim at strengthening some promising ongoing developments to harness opportunities of Big Data in health care. These include EU-wide initiatives in the area of health data standardisation, such as the Electronic Health Record Exchange Format[21] uptake, and in the field of data-related regulatory science, such as the HMA-EMA Joint Big Data Taskforce[22] 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) – considerably also in a federated manner – to facilitate R&I, promote collaboration among stakeholders, better promote health care processes and care flows. It will also support the development of better assistance systems for health care professionals to facilitate timely decision making during the course of the disease, 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 health care, therefore the participation of patients (or their representatives) and health care professionals is key in the design of related studies. Exploring the use of advanced analytics, using advanced services from European Research Infrastructures, EOSC-Life or other high-performance computing (HPC) capacities for digitalized research could be beneficial, in particular for very big research data or on the contrary for more scarce data spread over clinical centres in Europe, e.g. for rare diseases.

20 https://www.statista.com/statistics/1017863/worldwide-iot-connected-devices-data-size
21 Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019H0243
22 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

Potential outputs

- Contribution to developing data standards for health care, 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 pharmaceuticals companies, medtech companies, digital health solution providers, and academia, compliant with GDPR.
- Demonstrating the feasibility of using various health data sources in a federated manner and interoperable with EHDS for the subsequent testing, deployment and use of AI-based applications.
- Developed tools, technologies and methods for state-of-the-art data exploitation, respecting the FAIR principles.
- Developed methods and case studies to assess the performance of self-learning algorithms against current gold standards (e.g. reference data sets, baseline data of the "healthy" population, virtual population, ...).
- Training programmes organized on the use of new health IT tools and approaches for health care 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, public and private ones. 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 AI 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.
- A better insight into 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 leading to increased accuracy of diagnosis and efficacy of treatment, b) shorter times-to-market, c) wider availability of personalised health interventions to end-users.

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 health care solutions

Challenge

Although various initiatives[23] have already provided useful tools and methods to assess the added value of health interventions, emerging and converging technologies[24] pose additional methodological challenges, partly due to the fact that technology categories converge in ways that alter the delivery of health care[25]. Besides, a more integrated and people-centred approach would require assessing the contribution of individual technologies to the combined effect of the various health interventions delivered throughout the health care continuum. This raises methodological challenges such as (but not limited to) the development and consistent use of outcomes measures that matter to patients. In addition, implementation of technological innovations in health care systems should ensure that innovation responds to people's and health care systems' needs. Furthermore, effective and cost-effective implementation might 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 of individual health technologies applied throughout the health care continuum;
- to improve implementation of technological innovations in health care 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 health care setting;
- to assess the added value of those integrated solutions (technological innovation and ancillary services) and their impact on the implementation process.

While intended to be used to inform decision at various levels of the health care systems, those methods and tools will be based on common elements, in particular:

- Integration of the perspectives of the various stakeholders (patients, carers, health care providers, health care professionals, industry, HTA bodies, regulators, policy makers and payers);
- Integration of a societal perspective to capture the spill-over effects including indirect costs of health interventions within and beyond the health care sector;

23 E.g., EUnetHTA Joint Aaction 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

24 Such as combinations of drugs and devices, nanotechnology-enabled products, medical devices employ ing digital communication tools, health interventions partially relying on Artificial Intelligence or software programs.

25 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 real-world evidence in value assessment.

IHI will elicit from the different stakeholders the various value dimensions (such as e.g. 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 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 assess the value of the various health care 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 health care solutions.
In addition, by providing an exchange platform for all stakeholders (in particular the various 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 of innovative products combining different types of technologies.

Potential outputs

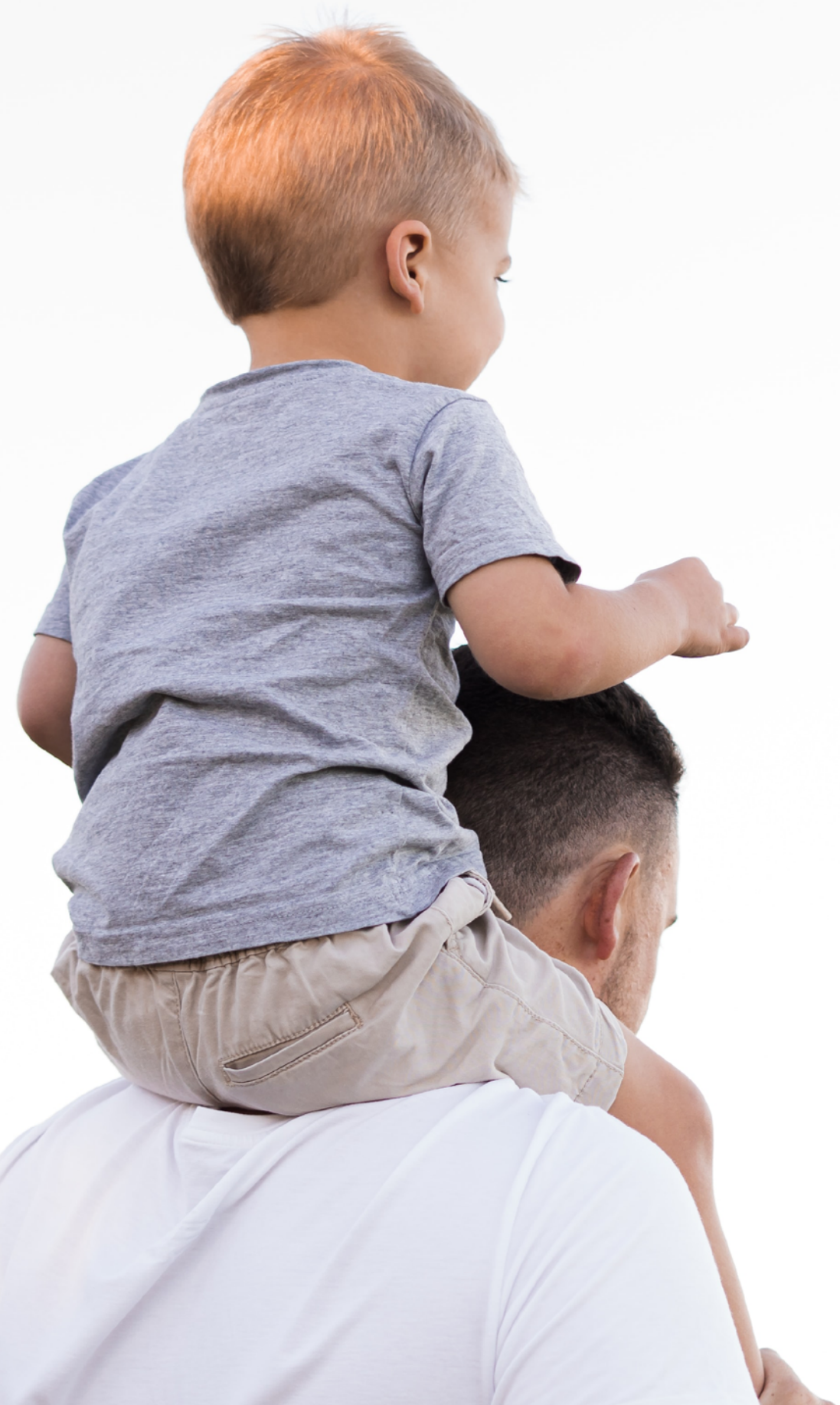
- Improved methods to transparently elicit stakeholder preferences regarding the various value dimensions and evaluation criteria.
- New and improved methodologies, tools and recommendations for evidence generation throughout the evaluation pathway to inform those value criteria. This will include collection 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, in order to determine their long-term effects on costs and outcomes for patients, health systems (including health care providers and health care professionals) and societies.
- Evidence-based strategies to improve the successful implementation of innovative technologies in health care settings as well as methods and tools to assess the effectiveness and cost-effectiveness of those strategies.

Expected impacts

- Seamless and successful implementation in health care settings of cross-sectoral innovations, integrated products and services delivering proven benefits to patients, health care systems and society as a whole.
- Patients have improved access to innovations that meet their needs and those of the health care systems.
- Better informed decision-making at different levels of the health care 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 in a positive effect on their R&I investments.

Chapter 3

Conclusions



Chapter 3
Conclusions

When it comes to the health of its citizens, Europe is facing a unique moment. The continent provides some of the best health care 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 health care solutions. However, the COVID-19 pandemic has shown the fragility of the system. Today's fragmented ecosystem confronted with the increasing complexity of health care innovation makes it harder to sustain this leadership position. Time has come to use the innovations both in biology/medicine and in digital technology, and to reap their benefits along the entire health care spectrum. This is one way to put Europe at the forefront of the implementation of the SDGs of the United Nations.

The 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 competence and skills along the entire health care value chain. IHI offers a unique opportunity by driving multi-sector collaboration to accelerate the development of citizen-centred health care innovations in areas of unmet public health needs.

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

The partnership will help strengthen the competitiveness of Europe's health industry, a cornerstone of Europe's knowledge-based economy and a tool for strategic autonomy, by bringing in new business models and ways of working, and lowering the risk of investing in the development of new products and services. It is likely to shorten the time-to-market of innovative products and services. It could also directly and indirectly create highly skilled jobs, both in academia and industry. Its contribution to improving the health of European citizens could also yield economic gains.

The partnership is likely to contribute to improved health outcomes for European citizens, expressed as more life-years in good health and more years independent, a lower burden of disease, improved patient understanding and experience of health care, better diagnostics and more efficient therapies leading to personalized medicine. It is expected to constitute an incentive for industry to invest in unmet public health needs, such as cancer and neurodegenerative disorders and diseases. The partnership is expected to contribute to citizen and patient buy-in of health care 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 health care 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 health care professionals will benefit from integrated pathways allowing delivery of streamlined care that addresses

their patients' issues. Companies will get access to innovative solutions and products from cross-sectoral collaboration; technology development will be de-risked; their probability of success will be improved. Academics and SMEs will be able to collaborate more easily. Overall, the sustainability and resilience of the whole health ecosystem – on which all these players 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 health care products or services, with demonstrated suitability for uptake by health care 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.

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 health care solutions;
4. exploit the full potential of digitalisation and data exchange in health care;
5. enable the development of new and improved evaluation methodologies and models for a comprehensive assessment of the added value of innovative and integrated health care 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 health care pathway (e.g. academics, health industry sectors, regulators, health technology assessment bodies, health care 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.

Annex II
Other candidate European Partnerships of potential relevance[26]

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 systems 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 health care.
Rare Diseases	Improve the integration, the effectiveness, the production and the 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-hows.
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.

26 Final determination depends on the confirmation of the scope of the partnerships. See full list https://ec.europa.eu/info/research-and-innovation/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/european-partnerships-horizon-europe_en

Name	Short description of the aim
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 & data infrastructure and support a highly competitive and innovative HPC and Big Data ecosystem.
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.

Name	Short description of the aim
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

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 assessing 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).

Case management: Intensive monitoring of a person with complex needs by a named case manager – usually a (specialist) nurse – through the development of care or treatment plans that are tailored to the needs of the individual patient who is at high risk socially, financially and medically.

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.

Empowerment refers to a process through which people gain or are afforded greater control over decisions and actions affecting their health and health care.
Health care providers encompass organisations that deliver health care goods and services. Typical health care providers are hospitals, long-term care facilities, providers of ambulatory health care, laboratories, nursing care facilities, pharmacies etc.

Health care 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 health care 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 health care.

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 health care 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 of accessing, understanding, appraising and applying health-related information within health care, 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) concerning a physiological or pathological process or state;
(b) concerning congenital physical or mental impairments;
(c) concerning the predisposition to a medical condition or a disease;
(d) to determine the safety and compatibility with potential recipients;
(e) to predict treatment response or reactions;

(f) to define 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 health care (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 health care 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 health care 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 o 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, health care 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 health care 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 health care 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 if 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 health care 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[27]. 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 informed and combined using an appropriate approach (e.g. cost-effectiveness analysis, multi-criteria decision analysis) so that to inform decision-making on the reimbursement, pricing, adoption, and implementation of health interventions. The report also addresses value in health care from the perspectives of all actors from patients and professionals/providers, to industry and Member States 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, https://www.europabio.org/
MedTech Europe: medical technology industries, from diagnosis to cure. www.medtecheurope.org
Vaccines Europe: https://www.vaccineseurope.eu/

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