**MAY 2022** 



# Unlocking Innovation to Build More Resilient and Sustainable Healthcare Systems in Europe

Summary of Research Findings



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# **Foreword**

EIT Health was established to tackle the EU 'health, demographic change and well-being' societal challenge by means of powered innovation. Its mission is to help overcome the EU paradox whereby state-of-the-art education, excellent research and a dynamic industry seldom turn breakthrough ideas into transformative innovation for citizens and patients. A meaningful connection between innovation and society lies at the centre of everything we do – it is only by working together with patients, citizens, innovators and entrepreneurs, healthcare professionals, academia and policymakers, that we can truly understand barriers, address challenges and leverage opportunities. To us, this ecosystem mindset is the steppingstone for innovation that is conducive of true value for society. It is also at the core of this work built on the insightful contribution of eighteen high-level experts from different countries and sectors.

Recent global developments have brutally shown the need for strong, yet flexible health systems. The COVID-19 pandemic has been an eye-opener and a sad reminder of the urgency to be better prepared for a wide range of challenges that may beset healthcare systems. It is also a testimony to Europe's and Europeans' extraordinary capacity to be resilient. The learnings from this event need to be translated into positive action so that we build more resilient and sustainable healthcare systems apt to anticipate - and hopefully avoid - future public health threats. In the words of the Jacques Delors Institute report "Towards a European Health Union", "robust and resilient health systems do not represent a cost. On the contrary, they are a long-term investment and a requirement of solidarity and prosperity". We also need to understand and embrace the essential role played by innovation and its untapped potential in strengthening health systems. This Think Tank report represents our contribution to spotlighting these matters and outlining a constructive way forward.

Interestingly, insights gained suggest that the challenges we face today are in large part not substantively new, but rather an exacerbation of previously identified issues intensified by the crisis. What is new is the sense of urgency generated by the pandemic and the evidence that barriers to innovation are by no means insurmountable technical, regulatory or resource impediments. This calls for a renewed sense of clarity around roadblocks, the need to address specific market failures which characterise the health sector as well as targeted recommendations for policies and investments that overcome cliches and inertia and allow for innovation to contribute to its highest capacity.



Despite the European Union (EU) having limited competence in health, the unprecedented wave of coordinated initiatives adopted following the pandemic and analysed in this report demonstrates new ambition and stamina. It testifies to the elevation of health as an EU priority in its own right.

There is now unprecedented momentum and willpower to address our health systems' weaknesses. EIT Health too, is beginning to reshape its strategic focus around a defined concept of 'flagships', focusing its portfolio on higher impact specific challenges laid bare by the pandemic, and thus manifesting true innovation power. This evolution acknowledges the concrete need to push for better coordination between actors to leverage different resources at scale under much more larger initiatives. This report is a call not to regress from the improvements made and an invitation to continue unlocking innovation to build more resilient and sustainable healthcare systems in Europe.

### **Jean-Marc Bourez**

EIT Health interim CEO, Managing Director EIT Health France



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# About EIT Health and the EIT Health Think Tank

EIT Health is one of eight Knowledge and Innovation Communities (KICs) of the European Institute of Innovation and Technology (EIT), an EU body and an Institutionalised Partnership under Horizon Europe's Pillar III – Innovative Europe. Established in 2015 to tackle the societal challenges of 'health, demographic change and well-being' within the EU, its mission is to help overcome the well-known EU paradox whereby state-of-the-art education, excellent research and a dynamic industry seldom turn breakthrough ideas into new transformative products and services.

Within the EIT Health network, ~150 partner organisations and institutions from academia, business, research and healthcare delivery collaborate across disciplines, borders and sectors to reinforce excellence, create knowledge and innovation, and encourage greater investment in innovation that delivers the outcomes that matter to citizens and patients. As a result, EIT Health represents a unique match between a sustainable innovation ecosystem model gathering and leveraging different partners and funding sources, and a change agent with extensive capacity to generate real-world data for evidence-based policymaking and the transformation of healthcare.

The EIT Health Think Tank is EIT Health's thought leadership forum. It brings healthcare leaders together to prepare the ground for life-changing innovation and to identify the next opportunity for a step-change in how healthcare is delivered. Subject matter experts collaborate across disciplines and borders to explore and assess the most pressing topics impacting health and the uptake and adoption of innovation. This allows for continual assessments of the environmental needs

of EIT Health's portfolio of projects and programmes. To facilitate this dialogue and its findings, EIT Health drives a range of activities to generate knowledge and insight, including research, expert round tables and interviews, publications, and dissemination of key information.

Previous EIT Health Think Tank's projects have focused on determining how to overcome the barriers to, and capitalise on the opportunities of the adoption of innovation and new technologies in healthcare, including the use of Big Data,<sup>1</sup> future-proofing Europe's digital health innovation pathway,<sup>2</sup> the role artificial intelligence (AI) can play in healthcare workforce and organisational transformation,<sup>3</sup> and the impact of the Medical Device Regulation (MDR).<sup>4</sup>

# **Executive Summary**

Building the resilience and sustainability of European health systems is not a new goal for the European Union (EU) and national governments. Yet, the COVID-19 crisis was an eye-opener globally on the need to better equip healthcare systems to respond to public health threats.

Steps in this direction include new impetus for the creation of an EU Health Union as well as a series of proposals aimed at strengthening the EU's health security framework and enhancing the EU's crisis preparedness and response capacity, including the revision of the mandates of the European Centre for Disease Prevention and Control (ECDC) and of the European Medicines Agency (EMA) as well as strengthening measures for Cross-Border Health Threats. These were followed by the establishment of the European Health Emergency Response Authority (HERA), a new European Commission department focusing on crisis preparedness and response measures, supported by a Recovery and Resilience Facility (RRF) to help mitigate the economic and societal impact of the pandemic, as well as the EU Health Programme (EU4Health) which injects €5.3 billion into innovation and implementation focused on supporting Member States in developing more resilient healthcare systems.<sup>5</sup> In parallel, the Conference on the Future of Europe has engaged EU citizens in a year-long democratic exercise to shape the future in a number of areas including health and digital transformation.

Reflecting these ambitions, the EIT Health Think Tank has undertaken a project to gather expert insight into the potential for innovation in health to support the creation of more resilient and sustainable healthcare systems in Europe by capitalising on the considerable benefits that innovation can provide. To date, the role and perspective of innovation in a holistic sense, integrating the wider societal (i.e. socio-economic) aspects of health, remain largely unexplored as a key factor in building resilient and sustainable healthcare systems.

This topic cannot be ignored in the wake of the COVID-19 pandemic, which highlighted inherent challenges of current healthcare systems' infrastructure and capability throughout the EU and demonstrated the powerful role of innovation in tackling the emergency and changing care delivery. These aspects need to be addressed and require investment to strengthen Europe's capacity to withstand future crises and ensure sustainability in the long term.

This EIT Health Think Tank research project 'Unlocking innovation to build more resilient and sustainable healthcare systems in Europe' gathers insights from academia, civil society, policymakers, industry, payers and providers on the role of health innovation across different sectors. The research was undertaken from August 2021 to January 2022 through analysis of written questionnaires followed by one-to-one interviews and a round-table discussion.

This report highlights existing barriers to the full deployment of innovation and presents research participants' recommendations on how innovation – understood as new solutions and processes, and importantly also as new ideas and perspectives –

can best build and support resilient and sustainable healthcare systems moving forward, either by developing, linking to and strengthening ongoing initiatives or by proposing new approaches to care delivery. Importantly, insights gained from this research have highlighted that the challenges we face today are in large part not substantively new, but rather an exacerbation of previously identified ones. These results call for a renewed sense of clarity around roadblocks and new targeted recommendations to realise common goals through enhanced collaboration between EU and national institutions, enhanced support for existing EU initiatives, and facilitation of new multi-stakeholder partnerships — all areas which EIT Health is keen to support.

Outputs of the discussions and policy recommendations are grouped under three key areas: (1) health system organisation and governance, (2) digitalisation, data and technology, and (3) policy and funding. At the outset, research participants established a baseline for the subsequent discussions by reviewing and analysing the accepted definitions of 'innovation', 'resilience' and 'sustainability' as they relate to the health systems. Insights into the current obstacles and opportunities to the adoption of technological and non-technological (e.g. organisational, societal) innovations in healthcare came through based on research participants' sector experience, and highlighted learnings from the COVID-19 pandemic both positive and negative – that must inform future healthcare policies. Key 'building blocks' were identified across the three areas identified above, which research participants felt were critical to sustainable and resilient healthcare systems. The research is supported by real-world case studies and 'best practice' examples of 'innovation in action'.



# Introduction

Innovation in health as a driver of resilient and sustainable healthcare systems is a concept which deserves the attention of policymakers and other stakeholders. This research focuses on the role of innovation in a holistic sense — one which integrates the societal (i.e. socio-economic) aspects of health — in building resilient and sustainable healthcare systems for a forward-looking Europe. Deployment of innovative technologies, solutions, policies and funding schemes has accelerated in response to the COVID-19 pandemic, making it essential to understand how these can or should be integrated into our health systems on a long-term basis.

Driving innovation and digital transformation in healthcare, and harnessing the benefits for patients, citizens and healthcare systems was already on the EU health agenda, portrayed by initiatives such as its research programme, Horizon Europe<sup>6</sup> and its Digital Health policy<sup>7</sup>. Nonetheless, the pandemic highlighted the immediate need for new, transformative innovative technologies and solutions to support public health8, while underlining the importance of data to allow collaboration and faster problem solving in a crisis. This has led to a renewed momentum for innovation in health, advancing clinical and regulatory science and health policies that encompass innovation, including medical devices and diagnostics, digital health applications, and the use of FAIR (Findable, Accessible, Interoperable, Reusable) data, to optimise delivery of care, care pathways and disease management. Ultimately, these changes aim to ensure that health systems are more agile, and better equipped to handle future crises and long-term needs. However, a review of the pandemic response across the EU has exposed key weaknesses in leveraging opportunities and new solutions. It has highlighted gaps in existing EU health policy and infrastructure, including fragmented approaches to the crisis, a lack of regional coordination, fragile healthcare systems and supply chains, and shortfalls in preparedness and planning.8

While COVID-19 triggered a complete overhaul of EU health policies, strategies to mitigate the wideranging effects on health systems, societies and national economies, are still evolving across the EU and lessons are still to be reflected in health system reforms. EU-level initiatives such as the EU Council Conclusions on Strengthening a European Health Union, and the new **European Parliament Special** Committee on the 'COVID-19 pandemic reflect the importance of leveraging takeaways from the pandemic to set out a range of measures that include the implementation of innovative solutions to help build resilient health systems<sup>6</sup>. Such actions are a testament to the shared competence that the EU and Member States hold in the field of public health, and an incentive to further reinforce this complementarity in the future.

Crucially, the crisis emphasised the need to strengthen a whole-of-society approach with innovation as a fundamental value to develop a sustainable future. EIT Health seeks to be a partner in supporting a process that involves all stakeholders by breaking down barriers, challenging the status quo and ensuring that innovation can lead to value-based, high-value care that responds to the needs of citizens, patients, healthcare systems and society as a whole.

# Methodological Note

### **Objectives**

The report gathers insights from literature and research participants across key stakeholder groups on their perspective of the role of innovation in building resilient and sustainable healthcare systems in Europe, particularly in light of lessons learned from the COVID-19 pandemic. It also provides recommendations as to how EU policy and funding for innovation can best support resilient and sustainable healthcare systems moving forward.



### **Analytical Approach**

The topic of unlocking innovation to build more resilient and sustainable healthcare systems in Europe was explored by analysis of written responses to a targeted questionnaire and one-to-one interviews with representatives of key stakeholder groups. The questionnaire and interviews explored key topics relating to innovation in healthcare, both now and in the future, including:

- How innovation and the resilience and sustainability of healthcare systems should be defined, taking into account the wider societal impact;
- Examples of the benefits innovation is already bringing to healthcare systems across different sectors;
- Opportunities and barriers that currently exist to greater uptake of innovation within healthcare systems across the EU;
- Lessons learned from the COVID-19 pandemic in relation to innovation in healthcare;
- The creation of resilient and sustainable healthcare systems to ensure they are optimally prepared for future threats.

Questionnaires and individual interviews were completed and analysed from August 2021 to January 2022. The process was conducted under the guidance of, and together with, EIT Health by FTI Consulting and Dr Karen Wolstencroft, Bluewolf Communications Ltd. Overall research findings were discussed and validated at a Roundtable Meeting of the research participants on 28 October 2021.

Findings are summarised in this report which also includes research participants' recommendations for action.

For clarity, the outputs of the discussions and recommendations were grouped into three key areas relevant to healthcare systems:

### 1. HEALTH SYSTEM ORGANISATION **AND GOVERNANCE;**

### 2. DIGITALISATION, DATA AND TECHNOLOGY;

### 3. POLICY AND FUNDING.

For the purposes of this research, and to set the context for the subsequent discussions, the generally accepted definitions of 'innovation', 'resilience' and 'sustainability' in the healthcare setting were also reviewed and discussed by research participants (see the appendix).

### Research Participants' Selection

The following stakeholder groups were invited to participate in the research to provide a broad spectrum of views representing all stages and sectors of the healthcare innovation pathway:

- 1. Academia, including Health Policy Research;
- 2. Civil Society;
- 3. EU and International Organisations;
- 4. Industry, Payers and Providers.



# Learning from the Pandemic to Unlock Innovation in Health

Experience gained from the COVID-19 pandemic has shone a spotlight on the strengths and weaknesses of healthcare systems across the EU. This has generated considerable discussion, analysis and impetus for strategic and financial initiatives to ensure systems are strengthened and better prepared for the future.<sup>8,</sup> 10,19,20

The COVID-19 pandemic also presented society with an unparalleled opportunity to assess the added value of innovation as a pivotal contributor to such an endeavour.

Indeed, across the EU, the uniqueness, speed and scope of the crisis generated an extraordinary need for new, readily available, ad-hoc solutions to address the lack of healthcare personnel and hospital capacity, as well as inadequate and fragmented access to

"The pandemic has given us some great lessons about what went wrong and identified opportunities to improve our health systems."

### Dr Jan Hazelzet

PROFESSOR EMERITUS OF HEALTHCARE QUALITY & OUTCOMES, ERASMUS UNIVERSITY MEDICAL CENTRE, ROTTERDAM medical equipment and medicines. Furthermore, diverted attention towards the immediate pandemic response, determined notable gaps in continuity of routine diagnosis, screening and care of patients, especially for those with long-term or chronic conditions.<sup>8</sup>

While recurring concerns about the potential negative impact of the rapid introduction of innovation in health should duly be recognised and addressed, research participants considered that the COVID-19 crisis represents a landmark for the recognition of both technological innovation and innovation with broader societal impact (care delivery, health system organisation, etc.) as fundamental for healthcare systems' resilience and sustainability. After all, medical innovation is as established as medicine itself with long accepted benefits for patients and healthcare systems. These include improved disease prevention through early detection, precision medicine through the development of new diagnostics and enhanced availability of health data and faster and more tailored care delivery by means of digital and remote-care solutions.

Within this healthcare landscape, already prone to innovation and reaping its benefits, the sense of urgency generated by the COVID-19 pandemic prompted a renewed sense for making the impossible possible. Financial, regulatory, logistical and cultural barriers were lowered at record speed.

Actions to mitigate risks of economic recession were undertaken swiftly and effectively, including redeployment of essential funds.<sup>8</sup> The regulatory pathway, often criticised for being slow and challenging, proved more agile and forward-thinking during the pandemic. Manufacturing and production capacity for medical countermeasures was boosted despite struggling global supply chains. Digital health tools moved from being viewed as a potential opportunity to becoming an immediate necessity, and their use increased substantially.<sup>22</sup>

"Without innovation, health systems are bound to existing ways of working, which may not be fit to meet needs of a changing environment."

### **George Wharton**

SENIOR LECTURER IN PRACTICE, DEPARTMENT OF HEALTH POLICY, LONDON SCHOOL OF ECONOMICS (LSE); PARTNERSHIP FOR HEALTH SYSTEM SUSTAINABILITY AND RESILIENCE (PHSSR)

"Innovation is not just about having a new idea, method or device, but is as importantly about how you adopt and implement the innovation within organisations from the ground up and in daily practice."

### **Josep Figueras**

DIRECTOR, EUROPEAN OBSERVATORY ON HEALTH SYSTEMS AND POLICIES

In short, positive examples of innovation implementation during the pandemic came to outnumber possible drawbacks and testified to the potential of overcoming challenges to implementation. Consequently, according to research participants:

- innovation must be seen as a legitimate means to achieve resilience and sustainability;
- innovation should be used not only to recover from the pandemic, but also as a long-lasting, forward-looking measure with key learnings from the crisis translated into positive action, particularly in the areas where significant headway has been made over the past 2 years i.e.
   (1) health system organisation and governance,
   (2) digitalisation, data and technology, and (3) policy and funding.
- successful examples of innovation implementation may inform the generation of a positive innovation ecosystem, with greater investment and accelerated access pathways for innovative solutions.

It is paramount that the changes and lessons learnt from the pandemic are truly put to action. The EU's attention and current and upcoming policy initiatives hold the promise and provide unique opportunities that cannot be missed to build better, more sustainable and more resilient health systems for the future.







The COVID-19 pandemic prompted a fundamental rethinking of healthcare system policy and planning and led to a renewed need to reconsider organisational structures and governance processes.

Research participants suggested that the major barriers to achieve the full potential of innovation include lack of leadership and fragmentation, which can be addressed by EU and/or Member States' interventions. Similarly, a study on health systems resilience during the COVID-19 pandemic undertaken by the European Observatory on Health Systems and Policies identified 20 key strategies that were able to enhance resilience during this challenging time. These relate to the need for strong leadership and governance, appropriate funding, support for the healthcare workforce, strengthening public health interventions, and transforming the delivery of

health services. Addressing these factors will help inform how obstacles to the full utilisation of existing innovation can be overcome.

### Leadership

According to research participants, healthcare systems are not necessarily ready to adopt change. Strong political vision and leadership in the Member States are required to move forward. To date, few countries in the EU have defined and executed long term plans addressing reforms to innovate in care delivery. This may be attributable to the lack of relevant education and skills to adopt innovation

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> FOCUS AREA 1: HEALTHCARE SYSTEMS ORGANISATION AND GOVERNANCE

and appreciate its long-term benefits. For instance, many healthcare workforces have limited digital health technology skills and insufficient awareness, up-to-date knowledge and technical skills required for successful deployment of innovation.<sup>30</sup> It is as important to invest in workforce skills and capabilities<sup>35</sup> as it is to invest in innovation itself – one is no good without the other.

The same applies to patients who should be fully proficient in health and digital literacy to co-create and co-deliver within the system.

EU action sets a positive precedent in this area. While the primary responsibility for health systems within the EU lies with individual Member States, the EU has many tools including funding streams (e.g. the EU Health program and Horizon Europe) and research partnerships (e.g. the EU Partnership on Health Systems Transformation) that can support the strengthening of health systems, and this support has become particularly important in the wake of the pandemic.<sup>29</sup> As part of the ongoing response and recovery efforts, the EU has launched a range of initiatives and legislative measures relating to healthcare policy and funding (see Appendix), which are intended to future health threat preparedness and to foster the resilience and sustainability of health systems of Member States.



"Due to the resistance to change, so far innovation has been mostly incremental without any disruption to the structure of health systems. We are wasting crisis after crisis."

### Alexandre Lourenço

PRESIDENT OF THE PORTUGUESE ASSOCIATION OF HOSPITAL MANAGERS, BOARD AND EXECUTIVE COMMITTEE MEMBER OF THE EUROPEAN ASSOCIATION OF HOSPITAL MANAGERS (EAHM), BOARD MEMBER OF THE EUROPEAN HEALTH MANAGEMENT ASSOCIATION (EHMA)

"Resilience is the ability to bend in certain directions if necessary. The pandemic is an excellent example – we should be able to bend and not to break."

### Jan Hazelzet

PROFESSOR EMERITUS OF HEALTHCARE QUALITY &
OUTCOMES, ERASMUS UNIVERSITY MEDICAL CENTRE;
MEMBER OF THE EIT HEALTH HIGH VALUE CARE FORUM
ADVISORY BOARD



Robust health system governance, based on improved competences and leveraged capabilities

# RECOMMENDATIONS FOR ACTION:

- Create governance structures which systematically include all relevant stakeholders including citizens and patients in consultation and decision-making. On the model of the European Medicines Agency (EMA), which involves patient representatives in its management board, authorities should consult patients in a systematic manner
- Leverage the additional EU and Member State tools and funding streams made available following the pandemic to prioritise and finance strategic investments in programmes to ensure effective workforce capacity and skills, including digital health education to allow for the digital transformation of health
- Expand European networks and learning communities for knowledge exchange on innovative experiences in health and social care as well as for technical assistance (e.g. European Reference Networks (ERNs) and Living Labs) and to support the creation of disruptive ecosystems of healthcare providers
- Carry out simulations which 'stress-test' health systems in different scenarios to identify potential vulnerabilities as well as preparedness plans and 'resilience testing' of health systems with coordinated approaches and indicators as proposed by e.g. the <u>European Commission</u> <u>Expert Group on Effective Ways of Investing in Health</u>

"Where there is a disconnection between academia, providers, public or private, and industry, EIT Health, through public—private partnerships, provides the possibility for collaboration."

### Alexandre Lourenço

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# Investment in effective disease prevention strategies

# RECOMMENDATIONS FOR ACTION:

- Member States should adopt and implement clear strategic plans for the adoption of innovation in healthcare systems, but also action to promote health beyond healthcare delivery, prioritising prevention, addressing lifestyle-related causes of disease and the social determinants of health
- Better planning for multiple scenarios and more coordinated epidemiological surveillance and early-warning systems will be vital to future preparedness, leveraging the coordination and funding opportunities provided by HERA



### Case study

# Virtual reality-supported intensive care training

During the pandemic, intensive care units (ICU) were often overwhelmed with coronavirus patients. Many doctors and nurses from other departments were willing to help, but working in ICU requires specialist training, and it can be challenging if volunteers don't have the right basic skills. Recognising this skills gap, the EU provided financing from the Emergency Support Instrument in order to establish a training programme for intensive care medicine together with the European Society of Intensive Care Medicine (ESICM), based in Brussels. The programme ran for 8 months and trained 17,000 doctors and nurses in 700 hospitals across the EU, who don't usually work in intensive care. The COVID-19 Skills PrepAration CoursE, or C19\_SPACE as it's known, is a free, two-part programme. It starts with



online events, videos and podcasts, and then moves to training sessions conducted by local intensive care research participants. The sessions are available in all EU languages and address the fundamentals of intensive care, such as the admission of a critically ill patient, respiratory support, sepsis and infections. They also explain how ICUs have operated during the coronavirus crisis. Some hospitals offer participants the opportunity to shadow an ICU expert for the day to get a full sense of how the unit works. Others offer the chance to follow clinical cases via a virtual reality immersion experience. With a virtual reality headset, doctors and nurses can watch an emergency unfold before their eyes, as if they were there.



### Fragmentation

Siloed and fragmented approaches are detrimental to innovation. In hospitals, there is frequently a limited capacity to collaborate across different departments. A focus on outcomes that truly matter to patients is often missing, which, coupled with the absence of standardised outcomes data, hampers the deployment of high-value care and of value-based healthcare models. This fragmentation spreads to healthcare systems where, for instance, the limited integration of health information systems and data interoperability put limits on the combination of digital technology and the exploitation of data to drive the health and care delivery process.

Still, one of the most important innovations in health system processes and thinking over the last twenty years has been an emerging new culture in the area of healthcare systems organisation and governance which places people in the centre. The definition of 'health' has progressed from a medical one to more comprehensive model that encompasses the wish of citizens and patients to function and live a life that they value. As a result, and notably during the pandemic, citizens and community groups have played a valuable and active role in the COVID-19 response, providing support, advice and information. Their continued engagement - as part of a whole-ofsociety approach - will be essential in helping to build resilience against future health challenges.<sup>23</sup>

"It is important to foster a 'bottom-up' approach to innovation, in which those involved in delivering healthcare as well as the end users (citizens and patients) are heard in shaping the agenda and developing solutions."

### Dr George Wharton

LONDON SCHOOL OF ECONOMICS; PARTNERSHIP FOR HEALTH SYSTEM SUSTAINABILITY AND RESILIENCE

"There has to be a plan for innovation that lays out a structure and resources and it has to be very targeted to ensure that it has a real impact and no loose ends."

### Birgit Beger

CEO EUROPEAN HEART NETWORK



# A comprehensive approach to health and social care

# RECOMMENDATIONS FOR ACTION:

- Involve regional and local authorities in an inclusive decision-making approach, scaling up the adoption of short decisional chains, as widely utilised during the COVID-19 crisis
- Adopt reforms for the integration of the healthcare and social care sectors, leveraging digital health and social care solutions e.g. bringing treatment of a chronic disease under 'one roof' and making treatment more effective and convenient for patients
- Prioritise and invest in strengthening primary care and the link with home care settings
- Invest in understanding, piloting and implementing patientcentred and value-based healthcare models





The project utilised a point of care testing solution across the entire pathway of patients needing anti-coagulation treatment (acute, outpatient, and at home). The solution enabled patients to consistently monitor their need for treatment, which led to a quantitative, qualitative and cultural value impact for stakeholders. For hospitals, a 10-20% reduction in emergency admissions is anticipated due to increased consistent patient monitoring, and a reduction in total cost of care/patient by shifting monitoring to outpatient/home care. Patient convenience is increased and there is a reduced burden to healthcare professionals due to at/near home testing. For the system/care pathway, the ability to build up data and analytics to test interventions enables the improvement of care pathways and symptom management, as well as the interconnectivity with secondary care. Patients are empowered to be more active and independent in own monitoring. For payers, those offering the solution, value-based procurement (VPB) led to an increased revenue per patient due to a full solution offering, jointly developing an integrated care solution within a long-term partnership model, data offering insights into clinical pain points and solution impact along care pathway, improved reputation for VBP (e.g. value claims supported by measured evidence).

### Case study

### **Zio Integrated Care Network, The Netherlands**

Zorg In Ontwikkeling (ZIO) is an integrated care network in the Netherlands that organises primary care for patients with chronic diseases through disease-specific bundled payments. It emphasises primary care and shifts tasks from the GPs and endocrinologists to nurse specialists and negotiates a single bundled payment contract from insurers to care providers for a defined package of care. Payments are therefore linked to quality measures creating an incentive to improve health outcomes with 10% of provider contracts allocated for performance-based financing. The results of the network are improvements in health outcomes and patient experiences (15% decrease in proportion of patients with poor glycaemic control) and reduction in the cost of care (54% decrease in hospital admission costs for patients assigned to specialty nurses). ZIO's care delivery model for disease management has helped guide national policy reforms for chronic care delivery implemented by the Dutch Ministry of Health.



"A fundamental problem is that innovation often lacks participatory co-creation with patients and providers involved. It's no longer about what is the matter WITH Mr Johnson but about what matters TO Mr Johnson."

### Prof. Jan De Maeseneer

GHENT UNIVERSITY DEPARTMENT OF PUBLIC HEALTH AND PRIMARY CARE; CHAIR OF THE EXPERT PANEL ON EFFECTIVE WAYS OF INVESTING IN HEALTH, ADVISING THE EUROPEAN COMMISSION

### Case study

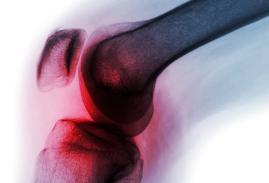
### Primary care reform in Flanders, Belgium

The Flanders region endorsed a reform of their primary care system which was the result of a federated policy aiming to achieve patient-centred integrated care, based on a participatory and bottom-up approach and engaging all stakeholders from the preparation to the implementation phase. The aims of the system change were: (1) to improve care for individual citizens, (2) to improve population health, (3) to create added value for healthcare professionals, (4) to create health gains for citizens in terms of cost and efficiency and (5) to increase inclusion and social justice. The implementation programme was structured as a set of 13 implementation projects. A central part of the reform was the creation of 60 Primary Care Zones (PCZ), each zone of on the average 100,000 inhabitants, coordinated by a Care Board, which contributed to integrating care at a local level and strengthening collaboration and coordination between local authorities, professionals, social welfare organisations, patient organisations, etc. In addition to the 60 PCZs, the reform developed a Flemish Institute for Primary Care. It also provided for more capacity in primary care and financial incentives for GPs, coordination of care and case management for people with complex care needs, and digitalised primary care with the development of integrated interprofessional platforms, encouraging health literacy and active patient and citizen participation.

# Social cohesion and whole-of-society approach

# RECOMMENDATIONS FOR ACTION:

- Make the 'European model' a reality with equal and affordable access
  to healthcare for all including promoting and funding research on
  equity of access to diagnosis and care as well as health literacy projects
- Encourage multi-stakeholder action (patients, providers, payers, industry), formalising and supporting citizen and patient involvement in co-creation of new models of care
- Foster inter-sectorial and public-private collaboration e.g. the new EU public-private partnership (PPP) Innovative Health Initiative (IHI) and the Innovation Procurement Platform (IPP)



### Case study

# JIGSAW-E: Joint implementation of guidelines for osteoarthritis in Western Europe

JIGSAW-E supports the systematic implementation of international guidelines and quality standards for osteoarthritis (OA) across six European collaborating sites in six countries. The goal is to ensure consistent care for OA, the most common chronic joint condition, and to help patients understand and self-manage their ailment. JIGSAW-E has introduced a new model of supported self-management in primary care pilot sites and evaluated its impact using audits of OA Quality Indicators – collected using an OA e-template – and routinely recorded general practice medical records. EIT

Health supported cross-fertilisation of ideas between SMEs, academia, citizens and clinical practice to support scale-out of this project.

JIGSAW-E is expected to impact OA patients and the carers who serve them with beneficial results such as strong citizen involvement and engagement, a network of patients who co-create solutions, international collaboration across sites of best practice and knowledge mobilisation that facilitates systematic service-level change.<sup>33</sup>





Advances in the medical and health technology sector depend directly on the deployment of innovation (e.g. the development of novel products and services, such as software or digital diagnostic tools).

Digital innovation, including eHealth, digital technologies and use of real-world data, has the potential to transform every aspect of healthcare and the care delivery pathway, delivering better value to patients<sup>27</sup>, if done in such a way as to avoid creating or adding to inequities in access for patients and healthcare professionals.

Research participants suggested that a number of barriers need to be tackled in order to realise a transformation towards data-driven healthcare.

"To reap the benefits of digitalisation we need to move from the technological perspective to delivering the services and organisational changes that embrace the digital technologies on the ground."

Marco Marsella, Ceri Thomson and Irina Kalderon Libal

DG CONNECT UNIT H3 - EHEALTH, WELL-BEING & AGEING

### Access, sharing and reuse of health data

Health systems across the EU are organised differently. Data-driven research and innovation, which largely benefits from shared databases and patient registries, are thus dependent on a multiplicity of data sources which can be used to create more precise, personalised pathways across regions and borders in a timely manner. Innovative policy and regulatory frameworks - such as the Data Governance Act and the European Health Data Space – are expected to bring significant improvements in this field.

This adds to several other data-related challenges faced by organisations when developing and implementing digital health solutions. These include: (1) challenges related to the various roles held by digital health stakeholders, (2) the range of regulations that apply to health data at multiple levels, and (3) the policies and practices that exist within the organisations concerning data use which intersect with the legal regulations and rules that apply to data processing. <sup>25</sup>

### **Data Protection and Governance**

A cohesive data framework requires a balanced system where access to data for research is complemented by a high level of data protection — this is a huge competitive issue for Europe. Health data specific regulation and ethical guidelines around the use of healthcare data are needed so that the full potential and predictive value of e.g. genomic and phenotypic data can be realised.

### Interoperability

Interoperability of data requires the adoption and implementation of common, and ideally open standards. Lack of interoperability determines obstacles in the re-use of data between healthcare organisations both with a single country and across borders.

A Redired Literation

"Keeping people healthy and managing diseases at home is a crucial factor in healthcare system resilience. Digital health plays a key role in achieving these goals."

### Thomas Allvin

EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES; MEMBER OF THE EIT HEALTH HIGH VALUE CARE FORUM



# Digital transformation of healthcare

# RECOMMENDATIONS FOR ACTION:

- Ensure a focus on digital solutions for health system innovation, investing in IT infrastructure, IT know-how of end-users (patients/ doctors), research and development that helps to accelerate digitalisation in health
- Support research and roll out of digital health focusing on technologies
  that could be transferable across diseases (e.g. isothermal nucleic acid
  amplification technology for detection of pathogens yields rapid results
  and is applicable across different infectious diseases) and ensuring that
  conventional patient pathways are reviewed to consider digital options
  and tools
- Deploy digital technologies, where appropriate based on AI learning, to improve health literacy of citizens and patients so that they can more easily adopt healthy lifestyles
- Integrate new digital and AI based solutions into disease
   management and treatment regimes, particularly for chronic diseases,
   for instance through virtual nursing support, personal monitoring or alert
   systems for patients which helps move care outside of the hospital
- Invest in new clinical processes, new skills, retraining and as needed new professions to ensure that the healthcare labour market can make best use of innovation

"Digital transformation of healthcare is not a mere digitalisation of healthcare systems, it expands beyond cost-effectiveness and entails the objective to maximise value to patients, focusing on increasing process efficiency and establishing high-quality patient-centred care. It can therefore be a tool and means towards achieving value-based healthcare."

### Dr Neda Milevska Kostova

VICE-CHAIR OF THE INTERNATIONAL ALLIANCE OF PATIENTS' ORGANISATIONS





### Case study

### The value of diagnostic information in cardiology

In-vitro diagnostic data can bring value to each step of the journey for patients with heart failure as well as other stakeholders in the healthcare system. The heart failure patient's pathway is often complex as they can experience both chronic and acute (requiring hospitalisation) stages of the condition.

A case study, conducted by MedTech Europe, the European trade association for the medical technology industry, explored how the use of information generated by in-vitro diagnostics, such as cardiac biomarkers, can address current shortcomings in heart failure care, e.g. missed or late diagnosis and suboptimal monitoring. Use of in-vitro diagnostic data allowed timely diagnosis and effective monitoring of patients, ultimately leading to better outcomes.<sup>28</sup>

### Scaling ICT based neurorehabilitation to personalised home care: RGS@HOME

The EIT Health supported project RGS@HOME developed a home version of Rehabilitation Gaming System (RGS), an existing commercial product utilised successfully in neurorehabilitation centres. Combining brain theory, AI, virtual reality and cloud computing, RGS@HOME uses games to assist patients with motor and cognitive recovery after a stroke. The solution will speed-up recovery and, by allowing for home treatment, it will drastically reduce the length of hospital treatment that patients require.

RGS@HOME is the result of more than 15 years of research in brain theory and the adaptation of ICT techniques to neurorehabilitation. The total investment executed to this point surpasses €10 million. EIT Health facilitated a partnership gathering public and industrial stakeholders from three European regions with both public and mixed private/public reimbursement models (Sweden, France and Spain).34

### Data-driven healthcare supported by EU policy and funding

# RECOMMENDATIONS FOR ACTION:

- Develop patient-centred and goal-oriented Electronic Health Records
  (EHRs) and data repositories that will allow easier sharing and
  portability of patients' health data between care providers including
  across borders and empower citizens by allowing quick and easy access
  to, and control of, their data
- Establish standards for EHRs at EU level, to make digital systems interoperable and facilitates the re-use of data for care or research across and between healthcare systems
- **Use the power of AI** to make the data held in EHRs more readily useable to identify optimal and personalised care for individuals and to facilitate greater mining of data to drive population specific health strategies
- Ensure political commitment to reforms across Member States and in support of the forthcoming European Health Data Space (EHDS), to provide a system for ensuring that health data is Findable, Accessible Interoperable and Reusable (FAIR) to facilitate improved therapies, patient pathways and outcomes
- Develop and support the trust of citizens, patients, clinicians, and researchers in health data and its use by **building principles of trust** (data protection, privacy etc.) into the design of future digital technologies
- Utilise real-world data and other 'big data' in machine learning and
  in algorithm development to optimise the use of scarce healthcare
  resources through the use of predictive modelling tools which allow for
  more targeted use of resources where their impact can be maximised,
  including in precision medicine and personalised care

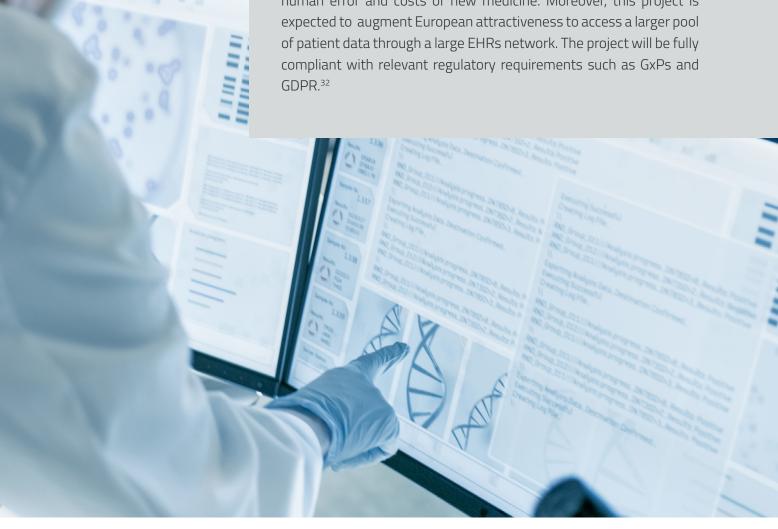




### Case study

# From electronic health records to electronic data capture systems

This EIT Health project aims to enable collection of clinical data from the electronic health records (EHRs) of several hospitals, to develop a system that can improve the efficiency of medical research, including research involving real world data. EHR2EDC (Electronic Health Records to Electronic Data Capture systems) data capture technique from the records of different hospitals would lead to 15% of previously manually entered data to be transferred automatically. The system would decrease the complexity and time spent on data entry and simultaneously reduce the workload of stakeholders, possibility of human error and costs of new medicine. Moreover, this project is expected to augment European attractiveness to access a larger pool of patient data through a large EHRs network. The project will be fully compliant with relevant regulatory requirements such as GxPs and GDPR.<sup>32</sup>



### Targeted data governance based on robust data access, sharing and security strategies

# RECOMMENDATIONS FOR ACTION:

- Ensure that the new frameworks to be created through the European Health Data Space are adopted at Member State level, with adequate resourcing and training, to allow data to be used to develop more resilient and sustainable health systems while at the same time ensuring that that sensitive health data are protected and trust in its appropriate use is maintained
- Ensure timely access to population level health data for the planning of pandemic response while respecting data protection provisions (e.g. GDPR): targeted guidance of the European Data Protection Board on data protection in COVID-19 responses should be re-visited and translated into EHDS and other new legal instruments that complement the GDPR
- Develop and coordinate a masterplan for an EU-wide architecture for federated analysis of FAIR (Findable, Accessible, Interoperable, Reusable), standardised health data by converging all existing projects in one direction

"Interoperability and data privacy are at the core of the policy debate and rightly so. Ultimately, however, they can only be resolved through decisive political action both to implement common data standards and to address the unavoidable trade-offs between data privacy and the use of that data for decision making."

### **Josep Figueras**

DIRECTOR, EUROPEAN OBSERVATORY
ON HEALTH SYSTEMS AND POLICIES



# A positive innovation ecosystem

# RECOMMENDATIONS FOR ACTION:

- Modernise the regulatory framework for the assessment of the efficacy and safety of new treatments, capturing learnings on flexibilities demonstrated during the pandemic and leveraging the current and upcoming EU legislative reviews (e.g. Pharma Strategy) to ensure innovation reaches citizens more quickly
- Ensure that the new governance framework to **facilitate re-use of data for research** is flexible and with minimum administrative overhead
  to encourage wide use of the data held in Electronic Health Records,
  disease registries and other data sources that will feed the European
  Health Data Space. This should take particular note of the needs of new
  and small business which have limited research budgets
- Create a collaborative environment encouraging ongoing dialogue
   between all stakeholders within society, including citizens and patients,
   policymakers and industry to study and suggest access pathways,
   reimbursement and procurement schemes and promoting innovative
   models of care

"Innovation is key to unlocking sustainable and resilient healthcare. Innovative solutions encompass technology which contributes not only to providing clinical outcomes but also to ensuring personalised and well-informed, high-value care delivery, hereby supporting the transformation of health systems and introducing the most advantageous economic and societal solutions in Europe."

### Yves Verboven

EXTERNAL CONSULTANT SENIOR ADVISER, MEDTECH EUROPE; MEMBER OF THE EIT HEALTH HIGH VALUE CARE FORUM ADVISORY BOARD

- Researchers and the medical device industry should collaborate to investigate the possibility of developing medical devices that are appropriate for low-resource settings
- Scale up use of innovative procurement models and available EU tools, e.g. <u>Public procurement of innovative solutions</u> (PPIs) and <u>Pre-commercial procurement</u> (PCP), to stimulate the adoption of innovative solutions into healthcare systems
- Create an innovation ecosystem on a global scale, where Europe engages in a dialogue with low- and middle-income countries, with a view to reduce inequalities of access and improve outcomes worldwide



# Accelerated and streamlined market access pathways for innovative solutions

# RECOMMENDATIONS FOR ACTION:

- Leverage EU initiatives, such as the EU proposed Pharmaceutical Strategy, and proposed new models such as the EIT Health suggested innovation pathway for digital health, to ensure accelerated and streamlined steps of the development journey of innovative solutions from idea to market
- Establish protocols for accelerated marketing authorisations to ensure that medicines and technologies effective against novel pathogens are brought quickly into use (as seen with COVID-19 vaccines)
- Leverage the forthcoming EU Health Technology Assessment (HTA)
   Regulation to ensure stronger and more structured cooperation in joint
   collaborative reviews carried out by HTA bodies to support national
   policy making e.g., regarding new testing and therapies for health threats



### Case study

# European Medicines Agency (EMA) COVID-19 pandemic task force

The EMA established the <u>COVID-19 pandemic task</u> force to support Member States and the European Commission in accelerating access to therapies and vaccines for the treatment and prevention of the coronavirus, including coordinating the regulatory steps required to develop, authorise and monitor the safety of new human medicines. Its activities include



the revision of potential candidate medicines to identify promising treatments, the coordination of preliminary discussions with developers, and the facilitation of clinical trials conducted in the EU. The task force's efforts have contributed to the swift development and introduction of multiple COVID-19 vaccines to European markets.

# Research and investment for initiatives to develop an 'innovation mindset'

### **RECOMMENDATIONS FOR ACTION:**

- EU and Member States should prioritise research and investment
  in innovation, with strong research funding governance and multiple
  innovation investment sources and the development of start-ups and
  scale-ups for innovative products in health, and promote innovation in
  health system management/organisation
- Promote and support the development of harmonised and comprehensive patient registries as well as the digital capability to enable evidence generated within health systems to improve the speed and efficiency of randomised controlled trials
- Use both quantitative and qualitative research methods to increase robustness of gathered data and subsequent results
- Improve global surveillance tools for the prevention and management of new threats and ensure access to comparable and complete real-time data for analysis



### Case study

### Telemedicine and remote monitoring for chronic health conditions

The COReHealth project was initiated by the Regional Agency for Health and Social Affairs in Puglia, Italy. The initiative uses innovative technologies to allow patients with chronic conditions to be treated from home, accompanied by self-management of their disease, thus reducing the need for hospitalisation and visits to clinics and doctors. Healthcare professionals are equipped with a cloud platform offering personalised patient monitoring (telemonitoring), teleconsultations, digitised services for personalisation and management of patient care plans and logistic/warehouse management of medical devices. Clinical teams provide patients with the necessary medical devices (tablet, oximeter, scale, etc.) that are used

for real-time measurement of relevant parameters. This allows constant detection and monitoring under a built-in automatic alarm system. A mobile phone app is available so patients can keep in touch with their doctors via video calls and chat, access video resources, allow easy visualisation of their therapeutic plan, and monitor treatment compliance. COReHealth is an innovative tool for patient care pathways allowing greater equity of access, continuity, and better quality of care, thus reducing the use of hospital resources and waiting times. COReHealth is now being used across different chronic health conditions, including diabetes, hypertension, and breast cancer.





Since the beginning of the Covid-19 pandemic, only minor improvements have been made in the implementation of innovation to support healthcare system resilience and sustainability. It is time to refocus on the role of new, targeted and innovation-friendly policies and funding mechanisms that can ensure not only the continued growth of innovative companies and organisations, but also the funding necessary to translate invention into implemented innovation.

In most countries, it has not been possible to return to the level of care in place prior to the pandemic, clearly highlighting the lack of any back-up systems or an ability to transform in times of crisis whilst ensuring continued care delivery. In addition, there is still a high level of distrust in innovative solutions, such as vaccines, by a substantial proportion of the population. Timely and pro-active mechanisms to adjust to these pressures are not in place, and so many health systems are still operating in crisis mode. These are all

important signals that there is an urgent requirement for interventions addressing challenges to innovation in order to achieve a systemic change and a significant improvement in healthcare system resilience.

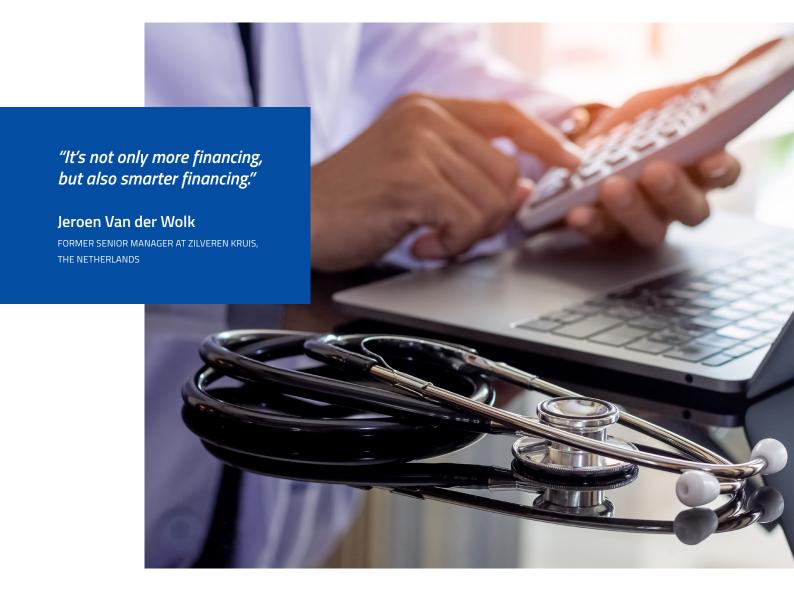
There is a clear opportunity for policymakers to play a vital role in defining public policies that allow and foster innovation to create resilience and sustainability in health systems. EU and national institutions are prioritising health in reaction to the pandemic and to prepare for future health threats. Policies need to be accompanied by effective implementation of plans for innovation which need to be funded sufficiently and systematically and be based on close cooperation from all stakeholders. Research participants outlined a number of hurdles in the policy/regulatory and funding domains.

# Fragmentation, regulatory rigidity and limited incentives

For traditional medicinal products and devices, the steps of the innovation pathway in EU Member States are relatively clear and well-defined. However, there appear to be limited experience and different approaches in regulatory assessment for innovative

health technology products. The approach to health technology assessment (HTA) across the EU is fragmented, with limited regulatory flexibility and adaptability to new technologies, and often patient outcomes and experiences – important contributors to the full value of innovation – are not considered. This seriously impacts the innovation pathway from development to adoption.

In addition, current payment models are outdated and can hamper healthcare transformation and impact achieving resilience and sustainability in health systems. Historically, reimbursement systems have been based on volume and payment-for-service rather than on mechanisms that focus on access, integration, cooperation and quality.<sup>26</sup> Today harmonised approaches for the assessment of innovative health technologies (such as digital medical devices) and appropriate reimbursement schemes are needed. The newly-adopted EU HTA regulation<sup>31</sup> aims to address some of these issues, but additional funding programmes dedicated to innovation and enabling the accessibility to innovative solutions are also required to overcome health systems inefficiencies in a durable manner.



# EU and national policy incentives

# RECOMMENDATIONS FOR ACTION:

- Adopt **robust policy and legislative frameworks** that facilitate:
  - A dynamic innovation ecosystem, leveraging Europe's capabilities and EU funding
  - Adequate investment in start-ups and scale-ups for innovative products in health
  - Mechanisms for the uptake of innovative digital solutions into healthcare systems with appropriate incentives
  - Uptake of common standards for health data exchange
  - The acquisition of digital skills by all stakeholders
  - Joint procurement of medical countermeasures
- Include the principle of goal-oriented care (where the life goals of citizens and patients are central to any intervention and moving away from 'disease oriented' approaches) in training, in practice, in financing and in quality assurance, to ensure there is an approach which uses patient priorities or goals to drive care choices



### Case study

### Improving funding and investment

EIT Health and the European Investment Fund (EIF) are partnering to operate the <u>Venture Centre of Excellence</u> (<u>VCOE</u>), a public–private co-investment programme to empower finance for European health small and medium size enterprises (SMEs).



## BUILDING BLOCK TO UNLOCK INNOVATION:

## Cross-border and cross-sectoral approaches

## RECOMMENDATIONS FOR ACTION:

- Enable greater cross-border collaboration through EU funded Joint Actions, joint procurement, and funding of EU agencies to develop new approaches including to reduce social disparities in health
- Develop and implement policy initiatives that encompass more than just the health sector utilising a multi-sectoral approach to think more widely, also promoting EU/international collaboration in health innovation
- EU institutions to increase the provision of technical assistance to help Member States become aware of the different tools and their potential to assist them in aligning objectives and processes

"From interesting projects and initiatives funded by the EU we can draw important lessons.

Often these projects remain as museum artefact – great experiences for participants.

The impact of these projects and dialogues that are happening in Brussels should be translated at regional and local level."

#### Giovanni Gorgoni

PRESIDENT OF EUROPEAN REGIONAL AND LOCAL HEALTH AUTHORITIES (EUREGHA)





#### Case studies

#### Promoting public-private partnerships

The Innovative Health Initiative (IHI) is a new proposed public-private partnership (PPP) under Horizon Europe. This initiative will help create an EU-wide health research and innovation ecosystem that facilitates the translation of scientific knowledge into innovations. It will cover prevention, diagnostics, treatment and disease management, and will work by bringing together diverse stakeholders (universities, companies large and small, and other health stakeholders) in collaborative projects that address disease areas where there is a high burden on patients and/or society. There will be a focus on cross-sectoral projects involving the biopharmaceutical, biotechnology and medical technology sectors, including companies active in the digital area.

#### Establishing a joint European research programme

The TO-REACH project, which concluded in May 2021, prepared the groundwork for establishing a joint European research programme on health services and systems that will contribute to the resilience, effectiveness, equity, accessibility, sustainability and comprehensiveness of health services and systems. The two main work streams of TO-REACH were: (1) to prepare, conceptually and methodologically, an international research programme on cross-border learning from good models of care and the conditions needed to transfer and implement these from one setting to another and (2) to enhance sustainable cooperation among funding bodies and their links with other existing or new funders' networks to facilitate such a joint international research programme.



#### Case studies

#### **Promoting innovation research**

The <u>candidate EU Partnership on Transforming Health and Care Systems</u> is the planned EU evidence-based initiative to provide multidisciplinary research and innovation actions in priority areas to fill knowledge gaps, produce evidence and develop guidance on how to transform health and care systems, develop new solutions to support and maintain people's health, strengthen collaboration between policymakers, users, professionals and researchers in and between different countries and regions, improve the ability of relevant health and care actors to take up innovative solutions, including organisational, service and policy innovations, and establish a platform to develop the ecosystems allowing for a swift scaling up and transfer of successful innovations to different health and care systems.



## BUILDING BLOCK TO UNLOCK INNOVATION:

# Adequate funding and investment for innovation in health systems

## RECOMMENDATIONS FOR ACTION:

- Ensure adequate resources for sustainable funding of healthcare systems and a balance of resources between social care, primary, secondary and tertiary care
- Increase predictable domestic allocation of resources and development
  of targeted policies to tackle NCDs, funding mechanisms such as
  taxation of unhealthy commodities, development of a framework that
  takes into account risk factors such as physical activity and healthy diets,
  tobacco and alcohol
- Promote healthcare financing models inspired by the objective of improving health rather than just reimbursing costs of treatment



#### Case study

#### Innovative procurement to improve outcomes

Patients with non-clear-cell renal carcinoma have a generally poor prognosis, standard treatment has limited efficacy, and there is insufficient use of precision medicine. The Capital Region of Denmark employed a value-based procurement solution focusing on patient outcomes, the total cost of the care cycle and also other factors, such as reduced burden on relatives and the collection of real-world data. This is expected to have benefits to patients in terms of personalised treatment options, prolonged life expectancy and improved quality of life. For the healthcare team this will reduce the overall cost of care delivery, allow them access to a wider range of treatment options and improve access to real-world data for research.



## BUILDING BLOCK TO UNLOCK INNOVATION:

Wide adoption of value-based healthcare (VBHC) models and innovative procurement models

## RECOMMENDATIONS FOR ACTION:

- Ensure that policies and investments focus on value-based healthcare
   (VBHC) models. A transition to VBHC financing will contribute to
   sustainable health systems by providing a realistic assessment of costs
   and outcomes across the care continuum
- Scale-up the adoption of value-based procurement across Europe, raising knowledge on existing experiences (see case studies)
- Expand use of EU tools that help foster the adoption of innovative solutions into healthcare systems. These include <u>Public procurement of innovative solutions</u> (PPIs) to allow the public sector to act as an early adopter of innovative solutions which are not yet available on a large-scale commercial basis, and <u>Pre-commercial procurement</u> (PCP) to stimulate innovation enabling the public sector to steer the development of new solutions directly towards its needs



## BUILDING BLOCK TO UNLOCK INNOVATION:

## Co-creation with citizens and patients

## RECOMMENDATIONS FOR ACTION:

- Using EU4Health programmes and other funding structures to include
   civil society organisations in EU policy making and EU funding projects
- **Support civil society organisations** on health topics, that make a critical analysis of health systems, but also contribute to health literacy, empowerment, support of informal care

"We have to make sure innovation is working for everyone."

#### **Hans Martens**

CHAIR OF THE COALITION FOR HEALTH, ETHICS AND SOCIETY & MEMBER OF THE HIGH VALUE CARE FORUM ADVISORY BOARD

## BUILDING BLOCK TO UNLOCK INNOVATION:

#### Leveraged EU funding to strengthen health systems and prepare them for future crises

## RECOMMENDATIONS FOR ACTION:

- Direct R&I focus and investments to the real needs of users, public health and health systems, leveraging instruments such as Horizon Europe, Innovative Health Initiative, the European Partnership on Transforming Health and Care Systems, HERA, EIT Health, European Innovation Council, European Regional Development Fund and InvestEU.
- Ensure horizon scanning for potential needs and allocate funds to prepare health systems for future crises and to improve health system financing, particularly the primary care sector. Funding provided by the EU Recovery and Resilience Facility (RRF), EU4Health, HERA and other EU streams offers a unique opportunity<sup>21</sup> to strengthen health systems.
- Ensure timely and inclusive policy debates on how best to leverage EU funding with a multi-stakeholder approach



## Conclusions

The results generated from this EIT Health Think Tank research project have expanded the knowledge base surrounding the importance of innovation in healthcare systems and how it can be optimised. They have also highlighted that the COVID-19 pandemic did not necessarily generate new hurdles, but rather exacerbated existing ones, while at the same time identifying new capacities to act quickly in bringing innovative solutions into healthcare systems.

Experts representing all steps of the health innovation pathway provided a critical analysis of the role of innovation, and of the current barriers and opportunities to the adoption of technological and societal innovations in healthcare across their respective sectors. They also outlined important key learnings from the COVID-19 pandemic that must inform healthcare policies moving forward. Recommendations for how EU health policies and funding schemes can best support the building of resilient and sustainable healthcare systems were proposed to help ensure that they are 'future-proofed' to be able to withstand upcoming health threats and crises. Research participants called on policymakers and all stakeholders to work together to adopt reforms that prioritise social cohesion, prevention, maintaining citizens' health and early detection of diseases.

In addition, the input of research participants pointed out the inertia and the difficulty in changing conventional pathways that characterises the healthcare workforce and systems. Tangible change would need considerable redefinition of the job requirements of doctors, nurses and caregivers — a major upheaval and shift in paradigm likely to face resistance. This is one of the major obstacles facing widespread uptake of innovation in health that became more evident during the pandemic. In light of this finding, experts call on decision-makers to break resistance to change and siloed approaches in health system organisation and management, promoting a bottom-up approach based on inclusive input from the workforce and co-creation with early and meaningful involvement of patients. Participants also underlined the opportunities of the digital transformation and the necessary legal frameworks, standardisation and dialogues to reap the benefits of data driven healthcare. These changes are to be supported by the opportunities provided through EU's funding of research and innovation and the widespread use of tools such as innovative procurement, and by a global and cross-sectoral dialogue of stakeholders at regional, national and supranational level.



While the impact of the COVID-19 pandemic was recognised as having an overwhelmingly negative effect on a global scale, some positive changes were also realised, not least the necessary increase in the use of better innovative solutions to deliver more rapid and more efficient care.

EIT Health has an ongoing commitment to health and innovation research, and these findings will help build on the insights generated from previous innovation-related Think Tank activities investigating the optimisation of health innovation pathways, the use of Big Data, the impact of artificial intelligence solutions in healthcare, and the challenges associated with the application of the Medical Device Regulation (MDR) to emerging technologies. The findings also align closely with the objectives of EIT Health's High Value Care Forum, a strategic initiative aimed at supporting healthcare providers and professionals to restructure healthcare delivery towards outcomes that have the highest impact and are of most importance to patients.

Innovative thinking was recognised as a crucial element of innovation and of ensuring implementation into health systems. EIT Health seeks to be a key partner in facilitating, developing and disseminating new ways of thinking, harnessing the combined knowledge and strength of its network.



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#### Appendix 1 - **Definitions**

For the purposes of this research, and to set the context for the subsequent discussions, the generally accepted definitions of 'innovation', 'resilience' and 'sustainability' in the healthcare setting were reviewed and discussed by research participants.

#### **Innovation**

Research participants were in broad agreement with the definitions of healthcare innovation developed by the World Health Organization (WHO) Health Innovation Group and by the European Observatory on Health Systems and Policies 12,13 (see Box – Definitions of Innovation) concurring on the fact that innovation has both technological and nontechnological dimensions, and that the results of innovation should always involve some degree of improvement.

Technological innovation is an umbrella term that comprises both product innovation (a product or service that is new or significantly improved) and process innovation (a new or significantly improved production or delivery method). Nontechnological innovations include organisational innovation (for example a new organisational method in business practices), workplace organisation or external relations, and can also include political, educational and societal innovation (defined as seeking new answers to social problems). 12 When technological improvements are coupled with non-technological innovation this can lead to societal transformation and change.

While the word innovation is more commonly associated with technological advances such as the delivery of better patient-centred care that addresses unmet needs and

#### **DEFINITIONS OF INNOVATION**

"Health innovation is to develop new or improved health policies, systems, products and technologies, and services and delivery methods that improve people's health, with a special focus on the needs of vulnerable populations."

- World Health Organization<sup>10</sup>

"Innovation requires a broad view, encompassing biomedical and technological innovation, organizational innovation and financing."

- European Observatory on Health Systems and Policies 11,12

improves outcomes, the non-technological dimensions need to be recognised. These are factors, beyond the effectiveness of the technology itself and include their wider economic, environmental and societal impact (e.g. increased equity in health).

#### Resilience

In broad terms, 'healthcare system resilience' describes a characteristic that can be developed in order to increase a healthcare system's capacity to absorb, withstand and recover from shocks and stresses. It encompasses the ability to prevent, respond to, and recover from acute and chronic crises, and minimising their impacts on health, social and economic well-being, including governance, financing, resources and care delivery models.





Based on an analysis of the existing literature and experience from the COVID-19 pandemic, the European Observatory on Health Systems and Policies proposed a definition of healthcare system resilience (see Box – Definitions of Healthcare System Resilience). In their analysis, they also identified 20 key strategies to improve resilience across four key health system functions: governance, financing, resources (both human and physical) and service delivery. Notably, around half of these strategies related to health system governance, highlighting its importance when planning future healthcare system resilience.<sup>15,16</sup>

In its report 'Assessing the resilience of health systems in Europe,' 17 the EU Expert Group on Health System Performance Assessment describes the concept of 'shocks' in relation to healthcare system resilience, namely the sudden and extreme changes that impact on a health system. 15 These generally have four stages: (1) preparedness, (2) shock onset and alert, (3) shock impact and management, and (4) recovery and learning. These are different from the predictable and enduring health system stresses, such as chronic diseases, co-morbidities and population demographics, which also need to be recognised and planned for.

#### **Sustainability**

While 'healthcare system sustainability' often describes the ability of a system to continually deliver its key functions over the long term, there does not seem to be an internationally agreed definition. The definition of healthcare system sustainability by the Partnership for Health System Sustainability and Resilience (PHSSR), which was launched as a collaborative effort between the London School of Economics (LSE), the World Economic Forum (WEF) and AstraZeneca in 2020 with the aim of improving population health, through and beyond the COVID-19 pandemic, builds on the WHO's definition of the function and objectives of health systems from 2000 (see Box – Definition of Healthcare System Sustainability).<sup>18</sup>

## DEFINITIONS OF HEALTHCARE SYSTEM RESILIENCE

- "The ability to prepare for, manage (absorb, adapt and transform) and learn from shocks."
- European Observatory on Health
   Systems and Policies<sup>14</sup>

## DEFINITION OF HEALTHCARE SYSTEM SUSTAINABILITY

"A health system's ability to continually deliver the key health system functions of providing services, generating resources, financing, and stewardship, incorporating principles of fair financing, equity in access, and efficiency of care, in pursuit of its goals of improving population health, and responsiveness to the needs of the populations it serves, and to learn and improve in doing so."

Partnership for Health System
 Sustainability and Resilience<sup>17</sup>





#### Appendix 2 - EU Healthcare Policy and Funding

#### TABLE A - European Commission initiatives - HEALTH POLICY

#### European Health Union

The <u>European Health Union</u>, based on lessons learned from the pandemic, aims to improve EU-level protection, prevention, preparedness and response against human health hazards. As the first steps towards building the EU Health Union, the Commission put forward a series of proposals aimed at strengthening the EU's health security framework and enhancing the EU's crisis preparedness and response capacity. The legislative package includes revising the mandates of the European Centre for Disease Prevention and Control and of the European Medicines Agency as well as introducing a proposal for a Regulation on serious cross-border threats to health (SCBTH), repealing Decision No 1082/2023/EU (the 'Cross-border Health Threats Decision').

#### European Health Emergency preparedness and Response Authority

The European Health Emergency preparedness and Response Authority (HERA) aspires to provide additional operational capacity through a permanent structure for risk modelling, foresight and horizon scanning, flexible manufacturing capacities, vaccine development and medical research. On 16 September 2021, the Commission unveiled the 'HERA Package' which consists of (i) a Communication introducing HERA; (ii) Decision establishing HERA; and (iii) Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency. In December 2021, a political agreement was reached on the Regulation. However, it cannot be adopted until the negotiations on the SCBTH are concluded. With the HERA Incubator already launched in February 2021, DG HERA became operational in September 2021.

#### Pharmaceutical Strategy for Europe

The Pharmaceutical Strategy for Europe, adopted by the Commission in November 2020, is a comprehensive and long-term plan aiming to ensure that patients have access to innovative and affordable medicines as well as to support competitiveness, innovation capacity and sustainability of the EU's pharmaceutical industry. The strategy envisages the revision of the General Pharmaceutical Legislation, to accommodate cutting-edge products, scientific developments and technological transformation. The strategy also addresses concerns highlighted by the COVID-19 pandemic, such as the resilience of supply chains for active pharmaceutical ingredients and medicines.



#### Europe's Beating Cancer Plan

Europe's Beating Cancer Plan further supports the build-up of a European Health Union. Cancer has become a priority on the Commission's agenda, indicated by the adoption of the first EU-level cancer strategy, the <u>Europe's Beating Cancer Plan</u> adopted in February 2021. The plan aims to prevent cancer and ensure that cancer patients, survivors, their families, and carers can enjoy high standards of diagnosis, treatment and a high quality of life. To achieve these goals, the lists ten flagship initiatives in the areas of (i) a Cancer Mission (EUR 4 bn funding for R&I), (ii) prevention; (iii) early detection; and (iv) diagnosis and treatment. The <u>Implementation Roadmap</u>, adopted in November 2021, allows the Commission to monitor the critical steps that need to be take to deliver the plan.

#### The EC Communication on enabling the Digital Transformation of Health and Care

The EC <u>Communication on enabling the Digital Transformation of Health and Care</u> includes three main pillars: (1) promoting secure access to and sharing of health data across borders, (2) better data to advance research, disease prevention and personalised health and care, and (3) advancing the use of digital tools for citizen empowerment and person-centred care.

Digital technology can increase efficiency, resilience of health and care systems, bring innovation, improve people's quality of life and encourage healthy living. The EC is supporting with its funding instruments (Horizon Europe, Digital Europe Programme, EU4Health), research and investment, and deployment and uptake of digital technologies in health and care.

## The European Health Data Space

Looking ahead, the adoption of a regulatory proposal to create a <u>European Health Data Space (EHDS)</u> is expected as one of the key priorities of this Commission in the area of health. The purpose of the EHDS is to promote health-data exchange, support digital health services and research on new preventive strategies, diagnosis and treatments of diseases, medicines, medical devices and health outcomes.

#### Important Projects of Common European Interest (IPCEI) on Health

IPCEI are large-scale European consortia in key strategic value chains characterised by close collaboration between companies. IPCEI have a strong focus on R&D and First Industrial Deployment. They have a special status under the EU's state aid regimes as they follow an "overriding European interest" and because such projects would not materialise due to inadequate market incentives. On 3 March 2022, the launch of an IPCEI on Health was announced. The project will have a focus on three strategic areas: (i) developing innovative and greener technologies and production processes for manufacturing medicines; (ii) innovating with regard to strategic challenges such as fighting antibiotic resistance, developing treatments for rare disease, and in collaboration with HERA, responding to future pandemics; and (iii) developing gene and cell therapies.

#### Global Gateway Strategy

In December 2021, the Commission unveiled a Communication on the Global Gateway Strategy. Albeit formally motivated by the experience of the COVID-19 pandemic, the Strategy fits into the EU's broader response China's Belt and Road Initiative and is part of a range of Connectivity Initiatives. According to the strategy, the Commission will aim to mobilise up to EUR 300 billion of investments between 2021 and 2027 for major investments in infrastructure development globally. One of the six key focus areas is health and the prioritisation of investments that can secure supply chains and strengthen local manufacturing capacities. To do so, the Commission will work together with partner companies to diversify pharmaceutical supply chains and help build up local manufacturing capacities. In this regard, HERA will play a role in addressing international supply chain bottlenecks and will aim to establish collaboration with global partners to reinforce surveillance, facilitate international cooperation. Through various activities, the strategy will facilitate investments in sustainable infrastructure and regulatory environment that promote cross-border research and innovation activities in order to address various disease such as COVID-19, malaria, yellow fever, Tuberculosis and HIV/AIDS.



#### TABLE B - European Commission initiatives - FUNDING

#### **NextGenerationEU**

NextGenerationEU is the EU's temporary stimulus package to support reforms and investments undertaken by EU countries to recover from the impacts of the COVID-19 pandemic.

## Recovery and Resilience Facility

As part of NextGenerationEU, the EU Recovery and Resilience Facility (RRF) presents a unique opportunity to make the EU more resilient from a social, economic and institutional perspective to support sustainable and inclusive growth. The facility has been established to provide funding to help mitigate the economic and social impact of the coronavirus pandemic across EU economies and societies, making them better prepared for future challenges. The RRF will provide up to €723.8 billion¹ in grants and loans to support investments and reforms in 2020-2026. To date, the Commission has received the national recovery plans from 26 Member States and has come to a positive assessment for 23 plans. The Commission has so far disbursed more than €56 billion to Member States in prefinancing payments.

Overall, Member States have shown a strong commitment to improving healthcare systems by including in their plans a wide array of health investments and reforms and supporting long-term care. These measures are to contribute to a variety of objectives, such as the improvement of primary healthcare, the transition from hospital care to outpatient care, upscaling of health prevention, the increase in the quality of diagnosing and treating patients, strengthening the healthcare workforce, modernisation of healthcare facilities and strengthening digital transition in healthcare.<sup>2</sup>

In terms of investments, Member States have included a wide array of health investments in the construction of new, or upgrade of existing, health infrastructures such as hospitals, centres for prevention, mental health facilities and laboratories. These investments are complemented by investments in modern medical equipment, such as medical devices for the diagnosis and treatment of cancer patients, strengthening overall resilience of the cancer prevention and care system.

The plans also comprise investments in primary care and prevention. They aim at increasing the allocation for primary care in rural areas and opening of new primary care outpatient clinics in deprived areas, introducing mobile pharmacies offering primary care services, and strengthening the role of general practitioners in primary care. Member States plan to adopt and implement an ambitious reform agenda to complement investments in the healthcare sector. This agenda features reforms to strengthen the resilience of the health sector and increase the availability of integrated and high-quality healthcare services. Key reforms focus on re-organising health systems to strengthen their capacity, improving the governance of health systems to increase sustainability of healthcare services, and establishing mechanisms to attract and retain health professionals in specific regions.

<sup>2</sup> For more information, see the RRF health thematic overview published here: <a href="https://ec.europa.eu/economy\_finance/recovery-and-resilience-scoreboard/assets/thematic\_analysis/5\_Health.pdf">https://ec.europa.eu/economy\_finance/recovery-and-resilience-scoreboard/assets/thematic\_analysis/5\_Health.pdf</a>



<sup>1</sup> In current prices.

> APPENDIX 2

Under the RRF, the total expenditure on healthcare-related measures amounts to approximately €37 billion for 22 plans, currently endorsed by the European Council, which corresponds to nearly 8% of the plans' total expenditure. In the recovery and resilience plans there is a clear focus on investments in digital health. Several recovery and resilience plans contain digital (e-)health measures that also contribute towards achieving the EU's target of allocating at least 20% of RRF budget to digital transition. Member States dedicate funds to investments in health information assets, digital upskilling and the transformation of healthcare delivery via telemedicine.

Below are some examples of the key focus areas of measures on health covered in Member States' RRPs, which gives an insight as to where national priorities lie when it comes to funding innovations for more resilient and sustainable healthcare systems.<sup>7</sup>

#### Focus area - Member States' emphasis within their RRPs

#### eHealth/ digitalisation

The strong emphasis from Member States on the digitalisation of healthcare systems is evident, for instance:

- The Belgian recovery and resilience plan includes targeted investments in eHealth solutions that aim to increase the quality, speed and agility of healthcare through the digitalisation of health processes. The plan includes the creation of standardized Care Sets for patient data collection and storage, the extension of the e-Prescription system and an integrated tracking system for the consumption of medicines and the operationalisation of teleconsulting. Belgium also outlined its intention to create a data system aligned to the Commission's requirements for the European Health Data Space.
- The French plan contains investments to support the digitalisation of the health system (eHealth). A comprehensive set of investments to accelerate the development of digital tools in the health sector is envisaged (e.g. speeding up the deployment of State information systems, the digital health platform and a one-stop shop for all digital services for healthcare professionals, upgrading the existing software to make them compatible with the necessary interoperability and security requirements, supporting and incentivising healthcare professionals in the digital transition.
- The Latvian plan includes, among other measures, a development of a Digital Health Sector Strategy to promote integrated and patient-centred healthcare, improve the accessibility, quality and resource efficiency of health services. This strategy should serve as a way forward to develop and deploy digital solutions in the health sector that are safe and meet the needs of the industry and its users.

### Primary healthcare and prevention

Some Member States' plans also include measures focusing on primary care and prevention. These measures aim at increasing the allocation for primary care in rural areas and opening new primary care outpatient clinics in deprived areas, introducing mobile pharmacies offering primary care services, and strengthening the role of general practitioners in primary care. For instance:

- The Greek plan includes a measure aimed at primary care and prevention. A reform of the primary healthcare system aims to ensure equal access to high-quality health services for all citizens. Furthermore, the reform envisages inclusion of the general medicine module in the curricula of a considerable number of medical schools and changes in the remuneration structure to attract more doctors to the primary health system. Lastly, the reform also aims to support the development of an integrated care system by establishing a framework for chronic diseases' management.
- Slovakia, Austria, Portugal, Luxembourg and others Member States plan to improve cooperation between various segments of care, scaling up prevention measures, reducing disparities in access to primary care services and resolve issues related to human capital strengthening.

### Healthcare system reform

Many Member States have a focus on healthcare system reform, including on physical assets, for instance:

- Cyprus intends to implement significant investments and reforms in the healthcare sector to increase its efficiency, accessibility and overall resilience. Key reforms focus on establishing a National Centre on Clinical Documentation, developing eHealth solutions and gradually shifting the healthcare provision and reimbursement framework towards value-based models.
- The Irish plan introduces a comprehensive health reform that aims to improve the accessibility, resilience, and cost-effectiveness of the healthcare system. The reform contributes to achieving a universal single-tier healthcare system wherein citizens have equal access to services. The reform also consists in operationalising Community Health Networks (CHNs) for the planning and delivery of primary healthcare services in a structured way.
- The Greek plan includes measures to create a comprehensive system of prevention whilst rationalising pharmaceutical spending and supporting pharmaceutical R&D.



#### **Horizon Europe**

Under Pillar 2 of Horizon Europe, Cluster 1 focuses on health and aims to deliver on the following topics: (1) staying healthy in a rapidly changing society, (2) living and working in a health-promoting environment, (3) tackling diseases and reducing disease burden, (4) ensuring access to innovative, sustainable and high-quality healthcare, (5) unlocking the full potential of new tools, technologies and digital solutions for a healthy society; and (6) maintaining an innovative, sustainable and globally competitive health-related industry. Among other objectives, Horizon Europe aims to make public health systems more cost-effective, equitable and sustainable, prevent and tackle poverty-related diseases, and support and enable patients' participation and self-management.

The European Commission's Horizon Europe Draft Work programme for 2023-2024 for the health cluster will focus on 6 themes:

- 1. Staying healthy in a rapidly changing society
- 2. Living and working in a health-promoting environment
- **3.** Tackling diseases and reducing disease burden, with HERA related topics having been granted its own sub-theme under this theme
- **4.** Ensuring access to innovative, sustainable, and high-quality care
- **5.** Unlocking the full potential of new tools, technologies, and digital solutions for a healthy society
- **6.** Maintaining an innovative, sustainable, and globally competitive health industry

#### **Digital Europe**

The <u>Digital Europe Programme</u> (DIGITAL) aims to build the strategic digital capacities of the EU and to facilitate the wide deployments of digital technologies, such as AI, HPC, Cybersecurity, Digital Skills and accelerate the wide use of digital technologies across the economy and the society, including in high impact areas of public interest, such as Health.

## EU Cohesion Policy funding streams

- Coronavirus Response Investment Initiative (CRII) and CRII Plus aims to provide immediate financial support to Member States for their most pressing needs arising from the coronavirus crisis as well as its long-term impact.
- The Recovery Assistance for Cohesion and the Territories of Europe (REACT-EU) regulation was adopted on 23 December 2020 and has allocated €50.6 billion in funding for Member States, to continue and extend the crisis response and crisis repair measures delivered through the CRII and CRII Plus, and constitute a bridge to the long-term recovery plan.

#### **EU4Health**

<u>EU4Health</u> 2021–2027 forms part of the Commission's response to the COVID-19 pandemic. The objective of the EU4Health programme is to go beyond the immediate crisis response and provide funding for measures to address the resilience of EU health systems. In its first Annual Work Programme for 2021, EU4Health includes plans for best practice sharing in primary care (Joint Action), for forecasting and planning workforce needs in the healthcare sector (Joint Action), as well as for setting up an EU health system resilience testing and support programme.