

# ANNEXES - KEY STRATEGIC ORIENTATIONS

## ANNEX 1 - HORIZON EUROPE CLUSTER 1 HEALTH

### 1. Global Challenges and Their Drivers

Diseases and disabilities pose a major socio-economic burden on citizens and health systems of the EU and worldwide. Non-communicable diseases, including mental disorders and illnesses, represent a major societal and economic burden and are currently responsible for up to 80% of health care costs in the EU<sup>1</sup>. This will further increase should the ageing society<sup>2</sup> not adopt healthier lifestyles and more effective health care approaches. Likewise, infectious diseases, including antimicrobial resistant infections, represent a major health risk to people as well as a serious cross-border health security threat for countries in the EU and worldwide. These challenges call for more health promotion, better disease prevention and more effective solutions to manage diseases and reduce disease burden as well as health care systems throughout the EU that are reformed to become more accessible, sustainable, resilient and efficient in promoting and protecting everyone's health and delivering health care of high quality to all citizens. To that end, new approaches for integrated and person-centred health care are required, which take into account specific needs of citizens and population groups throughout the life course, the influence of environmental, behavioural and socio-economic risk factors on human health and well-being, the opportunities offered by new tools, technologies, and digital solutions, and are built on a competent, reliable, secure and competitive European system of health care service developers, suppliers and providers.

R&I will be instrumental to develop these new approaches as well as to increase the knowledge, understanding and know-how that underpin innovation for promoting health and for preventing, treating and curing diseases. It will also require that new, better and more cost-effective health care services supported by innovative tools, technologies, and digital solutions become available that respond to the health needs of citizens and populations for

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<sup>1</sup> Non-communicable - or chronic - diseases are diseases of long duration and generally slow progression, and are the result of a combination of genetic, physiological, environmental and behaviours factors. The four main types of non-communicable diseases (NCDs) are cardiovascular diseases (like heart attacks and stroke), cancer, chronic respiratory diseases (such as chronic obstructed pulmonary disease and asthma) and diabetes. NCDs are by far the leading cause of death in the world, representing 63% of all annual deaths. NCDs kill more than 36 million people each year. Some 80% of all NCD deaths occur in low- and middle-income countries. <https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases>

<sup>2</sup> The share of the population aged over 65 on average across EU countries has increased from less than 10% in 1960 to nearly 20% in 2015 and is projected to increase further to nearly 30% by 2060.

promoting and protecting their health, preventing and managing their diseases, and assisting them in pursuing a longer, independent and active life in a rapidly changing society. Unleashing the full potential of digital technologies and health data will be a strong driver to achieve this outcome. Cooperation with other sectors will maximise societal benefits, drive innovation and ensure optimal impact. Accordingly, R&I interventions under Cluster 1 Health will be oriented towards the following six health-related challenges:

- Staying healthy in a rapidly changing society;
- Living and working in a health-promoting environment;
- Tackling diseases and reducing disease burden;
- Ensuring access to sustainable and high-quality health care in the EU;
- Unlocking the full potential of new tools, technologies and digital solutions for a healthy society;
- Maintaining a sustainable and globally competitive health-related industry.

These challenges are complex and interdependent. They have been chosen because they address key concerns and provide a clear perspective on what benefits people, patients and populations as well as institutional, social and economic stakeholders in the EU can expect from R&I interventions supported under this cluster.

### **Staying healthy in a rapidly changing society**

People's health and care needs are different, depending on their age, stage of life and social conditions.<sup>3</sup> Their physical and mental health and well-being can be influenced by their individual situation as well as the broader societal context they are living in. Furthermore, health education and behaviour are important factors. Currently, more than 790'000 deaths per year are due to risk factors such as smoking, drinking, physical inactivity, and obesity.<sup>4,5</sup> Income, education levels, social and gender aspects also have an impact on health risks and how disease can be prevented. Moreover, people's health can be impacted by a rapidly changing society, making it challenging to keep pace and find its way through new technological tools and societal changes, which both are increasing demands on the individual's resilience. In order to leave no one behind, to reduce health inequalities and to support healthy and active lives for all, it is crucial to provide suitable and tailor-made solutions, including for people with specific needs.

### **Living and working in a health-promoting environment**

The environment we live and work in has direct beneficial or negative impacts on human health and well-being. It is a major determinant of health, estimated to account for almost 20% of all deaths in Europe.<sup>6</sup> The factors causing these impacts on both physical and mental health are not all identified nor their effects comprehensively understood and accounted for in

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<sup>3</sup> For instance, the number of Europeans over 65 with age-related impairments is expected to grow from 68 million in 2005 to 84 million in 2020. It calls for new and tailor-made innovations that support the elderly in managing their impairment in daily life up to re-establishing body functions and capabilities.

<sup>4</sup> Health at a glance Europe 2018 (OECD, European Commission)

<sup>5</sup> A growing health threat for children and adolescents is overweight and obesity due to raising physical inactivity combined with unhealthy eating habits. Over 60% of children who are overweight before puberty will be overweight in early adulthood. Childhood obesity potentiates the risk for developing cardiovascular disease, type 2 diabetes, physical disabilities, orthopaedic and psychological problems, and underachievement in school. Obesity is one of the greatest public health challenges of the 21<sup>st</sup> century whose prevalence has tripled in many EU countries since the 1980s.

<sup>6</sup> WHO Europe: Environment and Health at <http://www.euro.who.int/en/health-topics/environment-and-health>

decision-making.<sup>7</sup> There are still considerable knowledge gaps in the understanding of the environmental, occupational and socio-economic risk factors for health and well-being. These risk factors include pollution, chemicals, noise, radiation, urbanisation, climate change, social injustice, changing work environments, and behaviour. Moreover, the determinants of a health-promoting environment need further understanding and evidence.

### **Tackling diseases and reducing disease burden**

Communicable and non-communicable diseases cause the greatest amounts of premature death and disability in the EU and worldwide. They pose a major health, societal and economic threat and burden for people. Many people are still dying prematurely and suffering from these diseases. Non-communicable diseases, including mental illnesses and neurodegenerative diseases, are responsible for up to 80% of EU health care costs.<sup>8</sup> These costs are spent on the treatment of diseases that are, to a large extent, preventable. Furthermore, although there is a huge potential for prevention, only around 3% of the health care budgets are currently spent on preventive measures. Infectious diseases, including antimicrobial resistant (AMR) infections, remain a major threat to health in the EU and global health security. AMR deaths could exceed 10 million per year worldwide according to some predictions.<sup>9</sup>

### **Ensuring access to innovative, sustainable and high-quality health care in the EU**

Health care systems in the EU are committed to provide people with universal access to good quality health care financed on the basis of equity and solidarity. They can contribute to economic prosperity and social cohesion in the EU. It is a main priority for the EU to support Member States in ensuring that health care systems are effective, efficient, equitable, accessible, and resilient while remaining fiscally sustainable in the medium and long term. With a view to this, the role and organisation of health care systems needs to be adapted and reformed to cope with societal trends and changes that include demographic, epidemiological, technological and environmental transitions.

### **Unlocking the full potential of new tools, technologies and digital solutions for a healthy society**

Technology is a key driver for innovation in the health and care sector. It can provide better and more cost-efficient solutions with high impact and can be tailored to the specific health and care needs of patients for improving their quality of life. However, novel therapies, technologies and approaches face specific barriers and hurdles in implementation and scale-up before reaching health care systems and patients, including societal issues. In addition, several emerging disruptive technologies and the availability of vast amounts of data and

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<sup>7</sup> Annually more than 400'000 premature deaths in the EU are caused by outdoor air pollution, mostly due to chronic diseases (with heart and lung being most affected) and respiratory infections. The heat wave that swept across Europe in 2003 resulted in 70'000 premature deaths. WHO estimated that the disease burden preventable through sound management of chemicals in the environment to around 1.6 million lives per year. Between 2030 and 2050, climate change is expected to cause worldwide approximately 250'000 additional deaths per year, from malnutrition, malaria, diarrhoea and heat stress.

<sup>8</sup> Currently, around 50 million people in the EU are estimated to suffer from two or more chronic conditions, and most of these people are over 65. Every day, 22'500 people die in Europe from those diseases, counting of 87% of all deaths. They account for 550'000 premature deaths of people of working age with an estimated €115 billion economic loss per year (0.8% of GDP).

<sup>9</sup> AMR is estimated to be responsible for 25,000 deaths per year in the EU alone and 700,000 deaths per year globally. It has been estimated that AMR might cause more deaths than cancer by 2050.

digitalisation offer big opportunities for transforming health and care and promoting health and well-being of citizens. Unlocking these opportunities depends on the capacity to collect, combine and make sense out of vast amounts of data, on the availability of appropriate regulatory frameworks and data infrastructures that will both safeguard the rights of the individual and of society, and stimulate innovation to develop impactful solutions. Due consideration of aspects of safety, effectiveness, appropriateness, accessibility, comparative value-added and fiscal sustainability as well as issues of ethical and legal nature will be crucial in order to translate these innovations into health policies, health and care systems, and clinical practice.

### **Maintaining an innovative, sustainable and globally competitive health industry**

The health industry is a key driver for growth and contributes to employment through high-value jobs and a positive trade balance, and has the capacity to provide health technologies<sup>10</sup> to the benefit of patients and providers of health and care services in Europe and worldwide. The development of novel health technologies is associated with high risks as it embraces the highest level of engineering combined with the complexity of life sciences. In addition, the health sector is strongly regulated, and many novel health technologies feature very long development times. Health industries, and in particular small and medium-sized enterprises (SMEs), may encounter difficulties to access the necessary investments, new markets and value-chains, or in setting-up partnerships and create alliances. Because health innovation impact healthcare, patients and society, the relevant value chains involve a broader variety of key players from supply, demand and regulatory side. A comprehensive approach relies therefore on cooperation and capacity building within a value ecosystem.

## **2. EU Policy Objectives**

The *health and well-being of its people* is a central aim of the European Union, its policies and programmes. According to Article 168 of the Treaty on the Functioning of the EU, high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities. With the proclamation of the European Pillar of Social Rights, the EU set the direction towards a fairer, inclusive and more social Europe for all European citizens based on a European social model that is fit for the challenges of the 21<sup>st</sup> century. Providing timely access to affordable, preventive and curative health care of good quality to everyone is amongst the key aspirations the EU and its Member States are aiming for, supported by dedicated regulations, policy strategies and programmes.<sup>11</sup>

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<sup>10</sup> WHO definition of 'health technology': A health technology is the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives.

<sup>11</sup> For instance: Directive on patients' rights in cross-border healthcare; political declaration on prevention & control of non-communicable diseases; EU decision on serious cross-border threats to health; Commission Communication on effective, accessible and resilient health systems; Commission Communication on upgrading the single market (and its proposed health technology assessments initiative); Council conclusions on nutrition and physical activity; Council conclusion on personalised medicine and pharmaceuticals; Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States; EU One Health Action Plan against Antimicrobial Resistance; Ostrava Declaration on Environment and Health; Commission Communication on the digital transformation of health and care; Council recommendation on strengthened cooperation against vaccine preventable diseases; Commission Communication 'European Plastics Strategy for a Circular Economy, Commission Communication 'Towards a Comprehensive European Union Framework on Endocrine Disruptors'; Commission Communication 'European Union Strategic Approach to

The EU is strongly committed to the UN Sustainable Development Goals (SDGs), many of which have an important impact on health and well-being, notably SDG 3 (Good Health and Well-being for People) with its nine health-specific targets aiming for universal health coverage for all at all ages by 2030, leaving no one behind, and ending preventable deaths. EU health-related actions aim to complement national health policies and thus support EU Member States in reaching those ambitious goals, which will not be possible without a massive investment in R&I at the national, European and international level.

### 3. Targeted Impacts

R&I supported under Cluster 1 aims to advance knowledge, build capacities as well as design, develop and demonstrate innovative solutions that will improve the health and well-being of people and support the transformation of health care systems. However, it will also depend on the actors on the ground – those receiving, supporting and delivering health and care services in local communities, regions and countries – to accept, support, take-up, scale-up and implement the recommendations and innovative solutions developed through R&I to achieve desired impacts. To maximise the benefits of EU investments and support the EU in achieving its goals, the cluster health will promote and unleash synergies with public health policies at national and regional level, with other EU programmes and policies, as well as with health-related European infrastructures. R&I activities under this Cluster shall target and contribute to the following interlinked, long-term impacts:

#### 3.1 Staying healthy in a rapidly changing society

R&I aims at supporting citizens in pursuing healthy and active lives by providing suitable and tailor-made solutions, including for people with specific needs. Targeted impacts are:

1. Pregnancy and birth is safer, maternal mortality is reduced<sup>12</sup>, preventable deaths of newborns and children under 5 years of age<sup>13</sup> are suppressed, and the physical and mental health and well-being of children (and their families) is improved.<sup>14,15,16</sup>
2. Citizens adopt healthier lifestyles and behaviours, make healthier choices (such as healthier food choices) and maintain longer a healthy, independent and active life with a reduced disease burden, including at old ages or in other vulnerable stages of life. They are able and empowered to manage better their own physical and mental health and well-being, monitor their health, and interact with their doctors and health care providers.<sup>17</sup>
3. Citizens' trust in knowledge-based health interventions and in guidance from health authorities is strengthened, including through improved health literacy, resulting in increased engagement in and adherence to effective strategies for health promotion,

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Pharmaceuticals in the Environment'; EU decision on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet'

<sup>12</sup> SDG3 target 3.1, 3.2, 3.7

<sup>13</sup> SDG 3 target 3.2

<sup>14</sup>SDG 3 targets 3.3,3.4 , 3.5, 3.7, 3.8 and 3a. WHO Framework Convention on Tobacco Control, the Tobacco Products Directive 2014/40/EU, WHO Europe Health 2020 A European policy framework and strategy for the 21<sup>st</sup> century

<sup>15</sup> EU Action Plan on Childhood Obesity 2014-2020,

<sup>16</sup> WHO Global action plan for the prevention and control of non-communicable diseases 2013-2020

<sup>17</sup> Commission Communication on the digital transformation of health and care.

diseases prevention and treatment, including increased vaccination rates<sup>18</sup> and patient safety.

4. Citizens are protected from health risks due to misinformation<sup>19</sup>, manipulation and fraud, including the sale, purchase and use of substandard, falsified<sup>20</sup> or inappropriate medicines.
5. Health policies and actions for health promotion and disease prevention are knowledge-based and targeted to citizens' needs.

### **3.2 Living and working in a health-promoting environment**

R&I aims at protecting citizens' health from negative impacts resulting from environmental and occupational risk factors. Targeted impacts are:

1. Citizens' health and well-being is protected and promoted, and premature deaths, diseases and inequalities related to environmental pollution and degradation are prevented.<sup>21,22</sup> In particular, the health threat and burden resulting from hazardous chemicals and air, water and soil pollution and contamination is reduced, including at the workplace, such that the related number of deaths and illnesses is substantially reduced by 2030.<sup>23</sup>
2. The EU's adaptive capacity and resilience to climate change-related health risks is strengthened.<sup>24</sup>
3. European cities and regions are healthier, more inclusive, safer, resilient and sustainable.<sup>25</sup>
4. Policy-makers and regulators are aware and better informed about environmental and occupational risk factors, including the combination of factors, for health and well-being across society.<sup>26</sup> Accordingly, knowledge-based policies at EU and global level better protect and promote citizens' health and well-being.<sup>27</sup>
5. Citizens understand better complex environment and health issues, and effective measures to address them and support related policies and regulations.<sup>28</sup>

### **3.3 Tackling diseases and reducing disease burden**

R&I aims at decreasing the burden of diseases on citizens and health care systems. Targeted impacts are:

1. Health burden of diseases in the EU and worldwide is reduced through effective disease management, including through the development and integration of innovative diagnostic

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<sup>18</sup> Council recommendation on strengthened cooperation against vaccine preventable diseases

<sup>19</sup> Commission Communication on Tackling online disinformation – a European approach

<sup>20</sup> Directive on Falsified Medicines

<sup>21</sup> Decision No 1386/2013/EU on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet', <http://ec.europa.eu/environment/action-programme/>

<sup>22</sup> Ostrava Declaration of the Sixth Ministerial Conference on Environment and Health of the WHO Europe, 2017, [http://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0007/341944/OstravaDeclaration\\_SIGNED.pdf?ua=1](http://www.euro.who.int/__data/assets/pdf_file/0007/341944/OstravaDeclaration_SIGNED.pdf?ua=1)

<sup>23</sup> SDG 3 target 3.9

<sup>24</sup> Ostrava Declaration of the Sixth Ministerial Conference on Environment and Health of the WHO Europe, 2017, [http://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0007/341944/OstravaDeclaration\\_SIGNED.pdf?ua=1](http://www.euro.who.int/__data/assets/pdf_file/0007/341944/OstravaDeclaration_SIGNED.pdf?ua=1)

<sup>25</sup> Ostrava Declaration of the Sixth Ministerial Conference on Environment and Health of the WHO Europe, 2017, [http://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0007/341944/OstravaDeclaration\\_SIGNED.pdf?ua=1](http://www.euro.who.int/__data/assets/pdf_file/0007/341944/OstravaDeclaration_SIGNED.pdf?ua=1)

<sup>26</sup> Ostrava Declaration of the Sixth Ministerial Conference on Environment and Health of the WHO Europe, 2017, [http://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0007/341944/OstravaDeclaration\\_SIGNED.pdf?ua=1](http://www.euro.who.int/__data/assets/pdf_file/0007/341944/OstravaDeclaration_SIGNED.pdf?ua=1)

<sup>27</sup> E.g. the EU's future 8th Environment Action Programme, follow-up to its Plastics Strategy and the Strategic Approach to Pharmaceuticals in the Environment, and the WHO environment and health process.

<sup>28</sup> Ostrava Declaration of the Sixth Ministerial Conference on Environment and Health of the WHO Europe, 2017, [http://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0007/341944/OstravaDeclaration\\_SIGNED.pdf?ua=1](http://www.euro.who.int/__data/assets/pdf_file/0007/341944/OstravaDeclaration_SIGNED.pdf?ua=1)

and therapeutic approaches, personalised medicine approaches, digital and other people-centred solutions for health and care. In particular, patients are diagnosed early and receive effective and cost-efficient treatment, including patients with a rare disease, due to effective translation of research results into new diagnostic tools and therapies.

2. Premature mortality from non-communicable diseases is reduced by one third (by 2030), mental health and well-being is promoted, and the voluntary targets of the WHO Global Action Plan for the Prevention and Control of NCDs 2013-2020 are attained (by 2025), with an immediate impact on the related disease burden (DALYs).<sup>29,30</sup>
3. Health care systems benefit from strengthened R&I expertise, human capacities and know-how for combatting communicable and non-communicable diseases, including through international cooperation. In particular, they are better prepared to respond rapidly and effectively to health emergencies and are able to prevent and manage communicable diseases transmissions epidemics, including within healthcare settings.
4. Citizens benefit from reduced (cross-border) health threat of epidemics and AMR pathogens, in the EU and worldwide.<sup>31,32</sup> In particular, the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases are contained and hepatitis, water-borne diseases and other communicable diseases are being combated.<sup>33</sup>
5. Patients and citizens are knowledgeable of disease threats, involved and empowered to make and shape decisions for their health, and better adhere to knowledge-based disease management strategies and policies (especially for controlling outbreaks and emergencies).
6. The EU benefits from high visibility, leadership and standing in international fora on global health and global health security, especially in partnership with Africa.

### **3.4 Ensuring access to innovative, sustainable and high-quality health care in the EU**

R&I aims at supporting health care systems in their transformation to ensure fair access to sustainable health care services of high quality for all citizens. Targeted impacts are:

1. Health and social care services and systems have improved governance and are more effective, efficient, accessible, resilient, trusted and sustainable both fiscally and environmentally, with health promotion and disease prevention at their heart, by shifting from hospital-centred to community-based, people-centred and integrated health care structures and successfully embedding technological innovations that meet public health needs.
2. Health care providers are trained and equipped with the skills and competences suited for the future needs of health care systems that are reformed, digitally transformed and equipped with innovative tools, technologies and digital solutions for health and care. They save time and resources by integrating and applying innovative technologies, which better involve patients in their own care, by reorganising workflows and redistributing

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<sup>29</sup> WHO Global Action Plan for the Prevention and Control of NCDs 2013-2020 (resolution WHA66.10). [https://www.who.int/nmh/events/ncd\\_action\\_plan/en/](https://www.who.int/nmh/events/ncd_action_plan/en/)

<sup>30</sup> Including for instance the following voluntary targets (against the 2010 baseline): A 25% relative reduction in the overall mortality from cardiovascular diseases, cancer, diabetes, or chronic respiratory diseases; Halt the rise in diabetes and obesity; An 80% availability of the affordable basic technologies and essential medicines, including generics, required to treat major non-communicable diseases in both public and private facilities.

<sup>31</sup> WHO global action plan on antimicrobial resistance, 2015.

<sup>32</sup> EU One Health Action Plan against AMR, 2017.

<sup>33</sup> SDG 3 target 3.3

tasks and responsibilities throughout the health care system, and by monitoring and analysing corresponding health and care activities.

3. Citizens play a key role in managing their own health and care, informal carers (i.e. unpaid carers) are fully supported (e.g. by preventing overburdening and economic stress) and specific needs of more vulnerable groups are recognised and addressed. They benefit from improved access to health care services, including financial risk protection, timely access to quality essential health care services, including safe, effective, and affordable essential medicines and vaccines.<sup>34</sup>
4. Health policy and systems adopt a societal approach for the evaluation of health interventions, the organisation of health and care, and decision-making.

### **3.5 Unlocking the full potential of new tools, technologies and digital solutions for a healthy society**

R&I aims at supporting the integration and deployment of innovation in health care systems. Targeted impacts are:

1. Europe's scientific and technological expertise and know-how, its capabilities for innovation in new tools, technologies and digital solutions, and its ability to take-up, scale-up and integrate innovation in health and care is world-class.
2. Researchers, innovators and health care providers use health data and Artificial Intelligence (AI) supported decision-making in a secure and ethical manner, respecting individual integrity and underpinned with public trust.
3. Better informed policies and tailored legal and ethical frameworks for the development of innovative health technologies, and better understanding of the societal impacts of innovative health technologies and the digital transformation of health and care.
4. Citizens benefit from targeted and faster research resulting in safer, more efficient and cost-effective tools, technologies and digital solutions for improved disease prevention, diagnosis, treatment and monitoring for better patient outcome and well-being, in particular through increasingly shared health resources (interoperable data, infrastructure, expertise).<sup>35</sup> Citizens trust and support the opportunities offered by innovation for health and care, are involved in their design and take part in informed decision-making, based on expected health outcomes and potential risks involved.

### **3.6 Maintaining an innovative, sustainable and globally competitive health industry**

R&I aims at supporting the health industry in the development of novel health technologies addressing public health needs and market opportunities. Targeted impacts are:

1. Health industry in the EU is more competitive, sustainable and growing, providing high-value jobs and contributing to economic growth, in particular SMEs, by tapping into new markets and providing European leadership in breakthrough health technologies and innovations.
2. Health industry in the EU, in particular SMEs, gain the ability to grow and reach a critical mass to develop innovative products and services and to tap into international value chains and international markets.

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<sup>34</sup> [SDG 3 target 3.8](#)

<sup>35</sup> Commission Communication on the digital transformation of health and care.

3. Citizens, health care providers and health systems benefit from a swift uptake of innovative health technologies and services offering significant improvements in health outcomes, while health industry in the EU benefit from decreased time-to-market.
4. Health industry is working more efficiently along the value chain from the identification of needs to the scale-up and take-up of solutions at national, regional or local level, including through early engagement with patients, health care providers, health authorities and regulators.
5. Health security in the EU benefits from reliable access to key manufacturing capacity, including timely provision of essential medical supplies of particularly complex supply and distribution chain.

#### 4. Key R&I Orientations

R&I supported under Cluster 1 *Health* should mobilise researchers from academic institutions, research organisations, small and medium enterprises, and large companies, as well as citizens and patients, patients associations, providers of health and care services and regulatory instances, in order to tackle the six health-related challenges and deliver on the targeted impacts. Moreover, pan-European research infrastructures<sup>36</sup> will be harnessed, including those identified by the European Strategy Forum for Research Infrastructures (ESFRI) and those established under the European Research Infrastructures Consortium (ERIC) regulation<sup>37</sup>, to strengthen the productivity of European health R&I and to support the development of effective, fiscally and environmentally sustainable solutions while promoting access to health innovation. In order to achieve the greatest impact and benefits for the health and well-being of its population, it is also essential that the EU continues its international efforts in cross-border cooperation, coordination and alignment. This includes major international initiatives and established multilateral networks, e.g., in the area of infectious diseases, non-communicable diseases, rare diseases, brain research, and -omics and environment and health. International cooperation and partnerships with third countries and other international partners are key for tapping the best expertise and know-how available worldwide, for leveraging a critical scale of resources, and for tackling global societal challenges. Infectious diseases outbreaks and the spread of antimicrobial resistance (AMR) do not follow geographical borders, environmental factors in an urban or rural context create similar exposure and experiences in different regions, and the burden of the ageing society as well as the challenges of treating health care data are not European challenges only. It will also be important that the cluster health can react swiftly and decisively to Public Health Emergencies of International Concern (PHEIC) declared by WHO and support urgently needed research. Seeking complementarities and synergies with the EU's external cooperation and trade policies will not only reinforce the links between research and implementation and support evidence-based policy-making but in particular amplify the uptake and deployment of R&I results and solutions and thus the impact of EU investments.

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<sup>36</sup> <https://www.esfri.eu/>

<sup>37</sup> Such as : European Life-Science Infrastructure for Biological Information (ELIXIR) <https://elixir-europe.org/>, European Clinical Research Infrastructure Network (ECRIN) <https://www.ecrin.org/>; European infrastructure for translational medicine (EATRIS) <https://eatris.eu/>; Survey of Health, Ageing and Retirement in Europe (SHARE) <http://www.share-project.org/>; European research infrastructure for biobanking (BBMRI) <http://www.bbMRI-eric.eu/>; European Social Survey (ESS) <http://www.europeansocialsurvey.org/>.

The following sections focus on what R&I interventions and results are needed to tackle the health-related challenges and contribute to achieving the targeted impacts.

#### **4.1 Staying healthy in a rapidly changing society**

R&I can provide a better understanding of specific health and care needs throughout the life course, and develop more effective solutions for health promotion and disease prevention, including for needs related to chronic health conditions, physical and mental disabilities, or age-related impairments. R&I can help people, as well as communities, in developing innovative services, policies and digital solutions, also ensuring that they are accessible, equitable and effective in preventing disease and promoting health. Key to achieving these objectives is the availability and accessibility of real-world health data, which will require appropriate support by research and data infrastructures.

This R&I orientation will support activities aiming at:

1. Better understanding of human health at various developmental stages and their impact on ageing, including individual factors affecting health and individual resilience to diseases.
2. Better understanding of specific health and care needs and better solutions for addressing those needs, including specific needs of people in vulnerable stages of life, people with physical or mental impairments, or of population groups in socioeconomic situations with structural disadvantages.
3. Personalised solutions for health promotion and disease prevention of individuals or stratified solutions tailored to groups, including for improved prediction and prevention of diseases before/at birth.
4. Development of digital tools applications and other solutions, including social innovation, fostering health literacy and empowering citizens to better manage their own health and well-being throughout their life course and to protect them from health threats, including for countering health-related misinformation, manipulation and fraudulent sales of substandard, falsified or inappropriate medicines and illicit drugs.

Areas of Intervention:<sup>38</sup> This challenge requires R&I actions under several Areas of Intervention (AoI) of cluster 1 but the centre of gravity lies with AoI 1.2.1. ‘Health throughout the Life Course’. It is closely linked to AoI 1.2.2 ‘Environmental and Social Health Determinants’.

Cross-cluster issues: Synergies with other clusters could be explored through broad cross-sectoral collaboration. For example with cluster 2 ‘Culture, creativity and inclusive societies’ on health inequalities or cluster 6 ‘Food and natural resources’ on the role of nutrition for health (incl. human microbiome, mal- and over-nutrition, safe food), personalised diets (incl. food habits in general and childhood obesity in particular) and the impact of food-related environmental stressors on human health (incl. marketing). Other possible synergies could be explored by cooperating on digital tools, telemedicine or smart homes with cluster 4 ‘Digital, Industry and Space’ or with cluster 5 ‘Climate, Energy and Mobility’ on urban health or on mitigating the impact of road traffic accidents and related injuries.

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<sup>38</sup> Areas of intervention are set in the proposed Specific Programme of Horizon Europe.

International cooperation: Similar health challenges and needs for health promotion and disease prevention are faced by other regions and countries. International cooperation should be sought and promoted in order to benefit from new knowledge and solutions as widely as possible.

#### **4.2 Living and working in a health-promoting environment**

R&I will produce the knowledge necessary to identify and assess the risks and benefits for health, and to enable health promoting and disease preventive policy actions. Results will support the EU's environment and health policies and overarching policy frameworks such as the future 8<sup>th</sup> Environment Action Programme, the EU Strategic Framework on Health and Safety at Work<sup>39</sup> and the European Environment and Health Process (EHP)<sup>40</sup>. The outcome will also contribute to the development of new and improved health interventions and technologies. In order to achieve sustainable impacts, R&I must provide solid evidence and stimulate its uptake into a large number of environmental, occupational, social and health policies at the EU, national and regional level. Strong collaborations across sectors and with other Horizon Europe clusters dealing with issues such as agriculture, food, environment, climate, mobility or urban planning will be needed to ensure that maximal societal benefits will be reached. Likewise, international cooperation, including at science-policy level, will be key to drive forward and tackle this challenge.

This R&I orientation will support activities aiming at:

1. Collection, combination and analysis of environmental, occupational and human health-related data, taking advantage of the exposome<sup>41</sup> approach.
2. Identification and characterisations of emerging and persistent environmental, occupational and climate change-related stressors.
3. Establishment and quantification of causal relationships between exposure to the identified stressors and health impacts.
4. Development of innovative methods to better estimate the economic and health costs of exposure to identified stressors and co-benefits of preventive actions across sectors.
5. Translation of research results into early warnings and evidence for regulatory preparedness, targeted at policy levels where action is needed.
6. Elaboration of cross-sectoral approaches to mitigate and prevent adverse health outcomes and promote beneficial health impacts, together with actors inside and outside the health area.

Areas of Intervention:<sup>42</sup> This challenge involves R&I actions under several Areas of Intervention (AoI) of cluster 1 and other clusters, but the centre of gravity lies with AoI 1.2.2. 'Environmental and Social Health Determinants'. It is closely linked to AoI 1.2.1 'Health throughout the Life Course'.

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<sup>39</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014DC0332>

<sup>40</sup> [http://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0009/341946/Annex2\\_20June.pdf?ua=1](http://www.euro.who.int/__data/assets/pdf_file/0009/341946/Annex2_20June.pdf?ua=1)

<sup>41</sup> The concept of the exposome refers to the totality of environmental exposures (diet, lifestyle, occupational and environmental factors) from conception onwards, including its external and internal components.

<sup>42</sup> Areas of intervention are set in the proposed Specific Programme of Horizon Europe.

Cross-cluster issues: Synergies with other clusters could be explored through broad cross-sectoral collaboration, for example with cluster 6 ‘Food and natural resources, agriculture and the environment’ on human biomonitoring, on healthy ecosystems and human habitats (incl. nature-based solutions health and well-being), or on the sustainable management of clean water, soil and air. Other possible synergies could be explored by cooperating with cluster 4 ‘Digital, Industry and Space’ on health-related space R&I for location-based services, geo-observation and monitoring (e.g. of pollution), with cluster 5 ‘Climate, Energy and Mobility’ on the surveillance, prediction and mitigation of the health impact of climate change or on concepts/technologies for smart and healthy homes, rural areas and cities, and with both cluster 4 and 5 on health impact assessment, e.g. the impacts on health and well-being of infrastructure, urban planning, transport or technologies.

International cooperation: Exposures to environmental stressors of relevance to human health are not confined locally but transcend national borders and are connected to global political and economic relationships and interactions. International cooperation is thus key to tackle this challenge effectively, including by cooperating with international actors and initiatives like the WHO and the WHO Europe environment and health process (incl. WHO European Centre for Environment and Health, Chemical Risk Assessment Network, Global EMF project); United Nations Environment Programme; US National Institute for Environmental Health Sciences; US CDC (NHANES biomonitoring programme); US Environmental Protection Agency; OECD (chemicals testing).

#### European Partnerships:

A partnership on chemicals risk assessment would be launched in 2022 to support the EU/national chemical risk assessment and management authorities by providing new evidence and methodologies and stimulate their uptake in regulatory processes. The joint research and innovation programme would address established chemical regulatory processes and facilitate their adaptation to and preparedness for persistent or emerging challenges. It would aim to strengthen European capacities in the areas of: human biomonitoring; environmental and food monitoring; toxicology and hazard assessments; exposure assessment; emerging chemicals; chemical mixtures; validation, standardisation and reference materials; risk assessment methodologies; data management and analysis; communication, dissemination and training; priority setting and sustainability. The partnership would not replace already existing mandatory reporting or monitoring schemes enshrined in EU regulations, but enrich them with new knowledge and tools where necessary. The partnership would contribute to the sustainability of the human biomonitoring platform developed by HBM4EU (2017-2021), by incorporating it into a wider chemical risk assessment initiative as recommended during the 2018 Human Biomonitoring conference. In fine, the partnership would provide an EU-wide research platform complementing the EU chemical regulatory system, thereby strengthening the EU-MS collaborations for chemical risk assessment and management.

### **4.3 Tackling diseases and reducing disease burden**

There is an urgent need for R&I on new prevention, diagnostics, vaccines, therapies, alternatives to antibiotics, as well as to improve existing prevention strategies to create tangible impacts. This will require international cooperation to pool the best expertise and know-how available worldwide, to access world-class research infrastructures and to leverage critical scales of investments on priority needs through better alignment with other funders of international health R&I cooperation. The continuation of international partnerships and

cooperation with international organisations is particularly needed to combat infectious diseases, including antimicrobial resistances, and respond to major unmet needs for global health security including the global burden of non-communicable diseases.

This R&I orientation will support activities aiming at:

1. Better understanding of diseases and their drivers, including the causative links between environmental and behavioural factors and diseases, and better evidence-base for policy-making.
2. Better methodologies and diagnostics that allow timely and accurate diagnosis, identification of personalised treatment options and assessment of health outcomes, including for patients with a rare disease.
3. Development and validation of effective intervention for better surveillance, prevention, detection, treatment and crisis management of infectious disease threats.
4. Innovative health technologies developed and tested in clinical practice, including personalised medicine approaches and use of digital tools to optimise clinical workflows.
5. New and advanced therapies for non-communicable diseases, including rare diseases developed in particular for those without approved options, supported by strategies to make them affordable for the public payer.
6. Scientific evidence for improved/tailored policies and legal frameworks and to inform major policy initiatives at global level (e.g. WHO Framework Convention on Tobacco Control; UNEA Pollution Implementation Plan).

Areas of Intervention:<sup>43</sup> This challenge requires R&I actions under several Areas of Intervention (AoI) in cluster 1 but the centre of gravity lies with AoIs 1.2.3. ‘Non-Communicable and Rare Diseases’ and 1.2.4. ‘Infectious Diseases’. It is closely linked to AoI 1.2.2 ‘Environmental and Social Health Determinants’.

Cross-cluster issues: Synergies with other clusters could be explored through broad cross-sectoral collaboration, for example with cluster 3 “Civil security for society” on health security/emergencies (preparedness and response, medical counter measures, epidemic outbreaks/pandemics, natural disasters and technological incidents, bioterrorism), or with cluster 4 “Digital, Industry and Space” on decision-support systems or on geo-observation and monitoring (e.g. of disease vectors, epidemics). Other possible synergies could be explored by cooperating with cluster 6 “Food, bioeconomy, natural resources, agriculture and environment” on health security and AMR (one-health: human/animal/plant health).

International cooperation: Effective international cooperation is essential to reduce disease burden and to protect people against cross-border health threats including the rise and spread of AMR and (re)emerging epidemics. The EU should continue its efforts to initiate and participate in cross-border coordination and integration of R&I. To address these challenges of global dimension, it will require international cooperation to pool the best expertise and know-how available worldwide, and enable a better alignment with actions in the rest of the world. This includes international collaboration with major EU and global initiatives in the area of infectious diseases (Global Research Collaboration for Infectious Disease

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<sup>43</sup> Areas of intervention are set in the proposed Specific Programme of Horizon Europe.

Preparedness, GloPID-R), non-communicable diseases (Global Alliance for Chronic Diseases, GACD), rare diseases (International Rare Diseases Research Consortium, IRDiRC), brain research (International Traumatic Brain Injury Research, InTbIR), personalised medicine (International Consortium for Personalised Medicine, ICPeMed), and -omics (e.g. the International Human Epigenome Consortium, IHEC, the 1 Million Genomes Initiative).

#### European Partnerships:

i) *“EU-Africa global health partnership to tackle infectious diseases”*: This R&I partnership would aim to increase global health security in sub-Saharan Africa (SSA) and Europe, by accelerating the clinical development of effective, safe, accessible, suitable and affordable health technologies as well as health systems interventions for infectious diseases in partnership with Africa and international funders. It will also support implementation research and health systems research for the uptake of new, improved or existing medical interventions. This partnership would be the successor initiative of the EDCTP2 partnership programme and be launched in 2021. It would be established as an institutionalised partnership based on Article 185/187 TFEU.

ii) *“Rare Diseases”*: This R&I partnership would aim to improve the lives of rare diseases patients. It would build on the results and experiences the ERA-Net E-Rare which was continued in the frame of the European Joint Programme on Rare Diseases (EJP RD). The EJP RD has been launched in December 2018 to further help in coordinating the research efforts of European, Associated and non-European countries in the field of rare diseases and implement the objectives of the International Rare Disease Research Consortium (IRDiRC). The proposed R&I partnership would be established as co-funded partnership programme, starting in 2024. iii) *“Translational health research”*: Several existing Horizon2020-funded partnerships involve the very same health R&I funders but are simply focused on different thematic priority areas. The proposed R&I partnerships would aim to establish a flexible and more effective coordination between programme owners (typically ministries) and programme funders (typically funding agencies) of the numerous networks established in the European Research Area (ERA) for Health and Well-being. It would focus on establishing a strategic research agenda and joint funding strategy between major European funders, public and private, on translational health R&I. and be established as a co-funded partnership , starting in 2023/2024.

Missions: The co-legislators requested a mission in the area of cancer. A mission board will advise the Commission on the specific scope and objectives of such a mission.

#### **4.4 Ensuring access to innovative, sustainable and high-quality health care in the EU**

R&I can help by supporting the development of innovative solutions for health care systems in all their various dimensions (e.g. governance, financing, generation of human and physical resources, health service provision, patient empowerment). In addition, R&I can provide decision-makers with new evidence, methods and tools to successfully implement those innovative solutions into their health care systems. It will in turn help to improve the governance of health care systems as well as to allocate resources according to people’s needs and preferences while delivering fiscal sustainability to make sure those needs can be met in the long-term.

This R&I orientation will support activities aiming at:

1. Innovative solutions to support reforms in health care systems (e.g. organisational models, innovative health service delivery models, integrated care models, long-term care; digitalised services, personalised approaches, financing models, including financing of health care systems, remuneration models, incentive mechanisms, new payment/reimbursement models of health technologies<sup>44</sup>, accelerated access models in case of health emergencies; human resources planning, education and training).
2. Methods, tools and demonstrated pilots for uptake and scale-up of innovation in health systems (e.g. technological and organisational innovation), as well as for their transferability/adaptation from one country/region to another.
3. Simulation models to support policy-making, taking into account the complexity and specificities of health care systems and the need to protect access and pursue long-term fiscal sustainability.
4. Innovative solutions to support people-centred health and care throughout the life course: innovative solutions improving citizen empowerment, access of citizens to their own health data, health literacy, self-care, informal care, and community care.
5. Framework for better interoperability between data sources and infrastructures, for sharing, access, use and analysis of real-world data that will in turn improve the efficiency of health care systems by strengthening their governance, informing policy development and decision-making, facilitating monitoring and evaluation of health interventions with due attention to security, data protection, privacy, interoperability, standards, comparability and integrity.
6. Innovative full health technology assessment methods (i.e. including all relevant aspects such as clinical effectiveness, cost-effectiveness, ethics, organisational aspects, etc.) to support better allocation of resources, including reinvestment from low to high value care for patients.
7. Methods to assess performance and efficiency of healthcare organisations and health care systems based on outcomes that matter for patients and carers, aiming at reducing health inequality and allowing for international comparability.
8. Identification of factors accounting for health care systems resilience in absorbing the impact of crises, such as the expected dementia raise, and accommodating disruptive innovation.

Areas of Intervention:<sup>45</sup> All R&I areas of cluster 1 are concerned but the centre of gravity lies with AoI 1.2.6 ‘Health Care Systems’. It is closely linked to AoI 1.2.1 ‘Health throughout the Life Course’ as well as AoI 1.2.5. ‘Tools, Technologies and Digital Solutions for Health and Care’.

Cross-cluster issues: Synergies with other clusters could be explored through broad cross-sectoral collaboration, for example with cluster 3 “Civil security for society” on health economics and economic models, on cost-effectiveness, fiscal sustainability and accessibility of healthcare, or on adaptation of public health systems to societal challenges (climate change, migration, demographic change) thereby contributing to building resilience. Other

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<sup>44</sup> WHO definition of ‘health technology’: A health technology is the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives.

<sup>45</sup> Areas of intervention are set in the proposed Specific Programme of Horizon Europe.

possible synergies could be explored by cooperating with cluster 4 “Digital, Industry and Space” on cybersecurity of (public) health systems, products and infrastructures of digitalised health and care, or on health impact assessment (e.g. related to consumer products, working place innovation).

International cooperation: Cross-border learning from practices and good models of care is key in this area of research. Research will benefit from cooperation with international actors: such as World Health Organization and public health institutes (e.g. Canadian institutes of health research and Agency for healthcare research and quality (AHRQ) in the United States that are already partners of EU-funded projects in health systems research).

#### European Partnerships:

i) “*Large-scale innovation and transformation of health systems in a digital and ageing society*”. This R&I partnership with health care systems owners/organisers and research funders aims at boosting research in policy, uptake and scale-up of innovations to accelerate transformation of national/regional health care systems. Specific objectives would be to provide evidence for innovative solutions that support cost-effective and fiscally sustainable health care policies, to build knowledge on the conditions for transferability and up-scaling of innovative solutions across and within EU countries, to develop and test a mechanism to support diffusion of innovative solutions, to define unmet needs of citizens and health and care systems and to establish an R&I platform that brings together health data across health care systems to enable data-driven policy. The partnership will built on the strategic research agenda developed by the Horizon2020-funded support action TO-REACH, will draw on the expertise and experiences from the Member States and network of regions involved in the European Innovation Partnership on Active and Healthy Ageing (EIP-AHA), the Second ‘Active and Assisted Living’ programme (AAL2), the InfAct Joint Action and work in synergy with the EIT KIC-Health. A strong synergistic link will be created with the European partnership on ‘Innovative Health Initiative’. It would be established as co-funded partnership and starting in 2021.

ii) “*Personalised Medicine*”: This R&I partnership would align priority setting and funding for research projects in the area of personalised medicine between the EU Member States and regions, associated countries and international partner countries. It would be the successor initiative of the Horzion2020-funded ERA-PerMed partnership and also build on the Horzion2020-funded actions in support of the International Consortium for Personalised Medicine (ICPerMed) led by several EU Member States. Based on the on the results and experiences with ERA-PerMed, the proposed HE partnership would continue to align national research strategies, promote R&I excellence, reinforce the competitiveness of European players in personalised medicine and enhance the European collaboration with non-EU countries, including by supporting collaborative innovative research projects through joint transnational calls for proposals. It would be established as co-funded or co-programmed partnership programme, starting in 2023.

Innovation Procurement: Innovation procurement is a mean to drive innovation from the demand side. Procurers (e.g. health care providers) are potential buyers of innovative solutions to public health interest needs that are not yet available, or in insufficient quantity, on the market. Innovation procurements can initiate innovation through the purchase of R&D services, when market solutions are missing, or boost the marketing of existing solutions for

early adopters. Innovation procurement can then open market opportunities for European companies, including SMEs.

#### **4.5 Unlocking the full potential of new tools, technologies and digital solutions for a healthy society**

R&I is needed on the large spectrum of tools and technologies for bio-medical research, prevention, diagnosis, therapy and monitoring. Managing benefits and risks of new technologies and due consideration of aspects of safety, effectiveness, inter-operability, appropriateness, accessibility, comparative value-added and fiscal sustainability and issues of ethical, societal and legal nature will be crucial in order to translate these innovations into health policies, health and care systems, and clinical practice responsibly. Moreover, cross-sectorial R&I could address specific unmet needs for health tools, technologies and digital solutions with limited commercial interest. Artificial Intelligence technologies have recently shown great promise for analysing high volumes of health data, with high potential for advancing biomedical research, personalised medicine and health care and for supporting health care systems in their clinical, organisational and logistical functions.

This R&I orientation will support activities aiming at:

1. New tools and technologies for biomedical research, prevention, diagnosis and therapy of diseases and tools for monitoring diseases as well as treatment progression are designed, developed, tested or validated for the benefit of patients and the health and care systems, including nanomedicines, advanced therapies, medical devices, digital solutions, Artificial Intelligence applications robotics, -omics and other data-driven interventions and procedures.
2. Health data accessibility and interoperability across the EU, including the free flow and secure exchange of health data, leaning on existing research infrastructures<sup>46</sup> as well as the creation of a European health cloud(s) for research purposes.
3. Improved risk-benefit ratio of the developed innovative tools, technologies and approaches owing to powerful digital solutions using and processing big data for better detection, diagnosis and monitoring of disease, including real-world data, for efficient value assessment.
4. Efficient up-scaling and production systems, including advanced manufacturing techniques, enabling targeted and personalized health interventions.
5. Improved health technologies and interventions based on digital solutions, which support timely health information and secure use of health data.
6. New data-driven approaches, computer models and -simulations and other digital solutions are developed, translated and optimised for the prevention, health care and person-centred care, including smart data infrastructures and AI-based data analytics.

Areas of Intervention:<sup>47</sup> This challenge will benefit from R&I actions under several Areas of Intervention (AoI) of cluster 1 but the centre of gravity lies with AoI 1.2.5 ‘Tools, Technologies and Digital Solutions for Health and Care’.

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<sup>46</sup> Such as the European Life-Science Infrastructure for Biological Information (ELIXIR: <https://elixir-europe.org/>), identified by the European Strategy Forum for Research Infrastructures (ESFRI).

<sup>47</sup> Areas of intervention are set in the proposed Specific Programme of Horizon Europe.

Cross-cluster issues: Synergies with other clusters could be explored through broad cross-sectoral collaboration, in particular with cluster 4 “Digital, Industry and Space” on: digitalisation of the health sector, incl. health technologies, medical devices and key enabling technologies; assisted, autonomous, independent and empowered living; smart homes; decision support systems; health impact assessment (e.g. related to consumer products, working place innovation). Moreover, R&I actions under cluster health may be inspired by research achievements under pillar 1 (Open Science) or may benefit from follow-on support under pillar 3 (Open Innovation).

Innovation Procurement: Innovation procurement is a means to drive innovation from the demand side. Procurers are potential buyers of innovative solutions to public interest needs that are not yet available, or in insufficient quantity, on the market. Public procurements can initiate innovation through the purchase of R&D services, when market solutions are missing, or boost the marketing of existing solutions for early adopters. Innovation procurement can then open market opportunities for European companies, including SMEs.

#### **4.6 Maintaining an innovative, sustainable and globally competitive health industry**

There is a need for cross-sectorial R&I (integrating medical technologies, pharmaceuticals, biotechnologies, digital health and eHealth technologies) to strengthen the single market, including by implementing the Digital Single Market strategy, supporting the standardisation policy, driving innovation from the demand side and providing evidence and guidelines for stakeholders and regulators to ensure take-up of innovations supports fiscal sustainability while protecting access.

The health sector is subjected to strict regulatory requirements that impose the demonstration of clinical benefit(s) and safety. This means additional development steps, uncertainties and a longer time to market. Support to studies for health assessment procedures, clinical performance demonstration, quality assurance schemes and standardisation are therefore important elements.

This R&I orientation will support activities aiming at:

1. Efficient innovation management strategies, including intellectual property, to translate breakthrough technologies into health care applications.
2. Efficient collaboration with regulatory authorities and health care providers for an optimal time to patient access.
3. Novel methodologies and metrics adapted to new tools, technologies, digital solutions and interventions for their assessment, validation and translation into health care practice, including ethical aspects, their societal effects and integration into regulatory frameworks, and for allowing swift access by health care providers, patients and healthy citizens.
4. Regulatory authorities supported with better methodologies and interdisciplinary approaches to assess new health technologies and interventions.
5. New European standards and quality assurance schemes developed for submission to standardisation bodies and implementation by stakeholders.
6. Safe and clinically validated tools, technologies and services developed and delivered by European health industry that meet the needs of citizens, patients, health care providers and systems.
7. Greener pharmaceuticals and health technologies.

Areas of Intervention: All R&I areas of cluster 1 are concerned but the centre of gravity lies with AoI 1.2.5. ‘Tools, Technologies and Digital Solutions for Health and Care’, while it is closely linked to AoI 1.2.6 ‘Health Care Systems’.

Cross-cluster issues: Synergies with other clusters could be explored through broad cross-sectoral collaboration, in particular with cluster 4 “Digital, Industry and Space” on: industrial R&I infrastructures (pilot plants, testing and simulation facilities, open innovation hubs); additive manufacturing (3D/4D printing) and other production technologies (incl. biomanufacturing); safe, smart and sustainable materials. Synergies could also be explored with pillar 3 “Open Innovation”, in particular the scheme of the European Innovation Council that supports breakthrough and risky innovations.

European Partnerships: The “*Health Innovation partnership*” (*Innovative Health Initiative*) will provide a cross-sectoral collaborative platform bringing the pharmaceuticals, diagnostics, medical devices, imaging and digital industries together with public stakeholders. It will contribute significantly to “*Enabling the digital transformation of health and care in the Digital Single market*” by supporting precompetitive R&I in areas of unmet public health and accelerating the development of people-centred health care innovations that can be taken up in health and care systems. It intends to overcome barriers that prevent exploiting the full potential of digitalisation and data exchange, through standards, methods and tools for interconnectivity and interoperability as well as to deliver tools, data, platforms, technologies and processes that enable the delivery of innovative health products and services to predict, prevent, intercept, diagnose and manage diseases more efficiently, that meet the needs of the end users and payers. A strong synergistic link will be created with the European partnership on ‘Large-scale innovation and transformation of health systems in a digital and ageing society’, thereby warranting the usefulness, transferability and the potential uptake of the developed health solutions into public health systems. This partnership would be the successor initiative of the IMI2 partnership programme based on Article 187 TFEU. It will be launched in 2021.

Innovation Procurement: Innovation procurement is a mean to drive innovation from the demand side. Procurers are potential buyers of innovative solutions to public interest needs that are not yet available, or in insufficient quantity, on the market. Public procurements can initiate innovation through the purchase of R&D services, when market solutions are missing, or boost the marketing of existing solutions for early adopters. Innovation procurement can then open market opportunities for European companies, including SMEs.

## **5. European Partnerships**

Partnerships provide mechanisms to consistently aggregate R&I efforts into more effective responses to the policy needs of the Union, developing close synergies with national and regional programmes, bringing together a broad range of actors to work towards a common goal, and turning R&I into socio-economic results. As such, they are powerful instruments to address global challenges by translating common priorities into concrete roadmaps and coordinated activities. EU-funded health R&I played a pioneering role in establishing and testing first approaches and forms of cooperation between public and private funders, both within Europe and at international level. Under the previous R&I programme, Horizon 2020 (2014-2020), 36% of the budget allocated to collaborative health R&I was invested through European health R&I partnerships (€2.680bn of €7.472bn).

For the requested rationalisation and reform of European partnerships under Horizon Europe, the following two considerations were taken into account under Cluster Health, mainly to increase the openness and reduce the number of partnerships:

1. Widening the scope and/or objectives of partnerships, e.g.
  - to facilitate the participation of low performing countries
  - to extend private sector participation and improve leverage of funding
  - to set the ground towards better uptake and systemic impact of related R&I
2. Discontinuation and merging partnerships
  - to simplify the funding landscape, improve coherence and increase transparency
  - to create (additional) economies of scale

Following these considerations, the following five co-funded European partnerships are proposed for the first four years of Horizon Europe:

1. “Large-scale innovation and transformation of health systems in a digital and ageing society” (as of 2021);
2. “Chemicals risk assessment” (as of 2022);
3. “Translational health research” (as of 2023/2024);
4. “Personalised Medicine” (as of 2023);
5. “Rare Diseases” (as of 2024).

In addition, two institutionalised European partnerships (based on Article 187) are proposed in the area “Faster development and safer use of health innovations for European patients, and global health” set by the legislator:

1. “EU-Africa research partnership on global health security to tackle infectious diseases” (as of 2021);
2. “Innovative Health Initiative” (as of 2021).

On the one hand, These partnerships provide significant leverage of investments and alignment on common priorities which allow sharing expertise, resources and the financial risks involved and thus achieving critical scales that a single member state or company would not be able achieve alone. On the other hand they allow raising awareness and attracting interest from policy-makers, stakeholders and the wider public as well as gaining support from additional partners. As opposed to regular calls for proposals, a European partnership can bring together a broader spectrum of stakeholders, both private and public, to align agendas across industrial sectors and/or public policies with a higher level of commitment and over a longer time-scale to implement activities needed for major changes and impacts. Regular calls for proposals will neither achieve the same level of coordination, alignment or integration nor allow the same level of sharing of resources, responsibilities and financial risks involved. This is particularly true in cases where the number of disease cases (individual patients) is low, such as for rare diseases, or in cases where the market prospects (return of investments) do not match the financial risks involved, such as for poverty-related and neglected infectious diseases. Moreover, maximizing the impact on the health and well-being of citizens, patients or health systems requires building a long-term strategy and annual programming for a wide range of activities including research, innovation, networking, training, demonstration and dissemination, which is not possible through traditional collaborative projects.

## 6. Missions

One of the main novelties of Horizon Europe is the introduction of missions; high-ambition, high-profile initiatives which will put forward concrete solutions to challenges facing European citizens and societies. Missions are currently in the process of being defined within five areas:

- adaptation to climate change including societal transformation;
- cancer;
- healthy oceans, seas, coastal and inland waters;
- climate-neutral and smart cities;
- soil health and food.

Accomplishing missions will require a cross-cutting approach, drawing on research and innovation activities defined not only through individual Clusters, but across Horizon Europe and beyond. Research and innovation activities within this Cluster thus have the potential to support missions in all of the above-mentioned areas. The synergies between each mission and cluster will be further explored as possible missions take shape.