Version for public consultation – 23 October 2019

DRAFT Strategic Research Agenda
European Partnership for Health Innovation

Contents

This draft document sets the general framework for activities to be conducted in a potential new public-private European Partnership for Health Innovation under Horizon Europe. It is the result of discussions between the following associations representing the pharmaceutical and medical technology sectors: EFPIA, COCIR, MedTech Europe, EuropaBio, and Vaccines Europe. The ideas developed in this document will be implemented in collaboration of various industry sectors, together with patients, and citizens, academia, research organisations, healthcare professionals, public authorities. We are seeking research & healthcare stakeholders' views and contributions on the content of this document here or via contact@EUHealthPPP.org until 24 November midnight.

Chapter 1: Summary of vision for the cross-sector partnership

Healthcare in Europe is at a crossroads. It faces increasing challenges on a number of fronts; at the same time, technological and scientific advances offer new opportunities to solve these challenges. Bridging the gap to address health and translational challenges described below will require a multi-sector Public-Private Partnership to address the Sustainable Development Goal number 3 of the United Nations.

Healthcare in Europe faces multiple challenges

Healthcare has always been one of Europe's success stories: keeping citizens in good health has an economic value as well as is an end in itself. But it is under challenge on three fronts: a rise in non-communicable diseases driven in particular by the ageing of the population; a rise in infectious diseases driven amongst others by climate change; and cost pressures. European healthcare systems will soon no longer be sustainable.

The rise in **non-communicable diseases** stretches across the areas of cancer, mental, neurodegenerative, metabolic disorders (e.g. diabetes); respiratory diseases; cardiovascular and autoimmune diseases; chronic pain. Ischemic heart disease, stroke and lung cancer are the top three causes of death in Europe[1], with the importance of fighting cancer highlighted in the political guidelines of new European Commission[2] Age-related disorders are on the rise[2,3], with dementia being a main component[3]. Mental disorders overall represent a very high economic burden to society[4]. Evidence is increasing for a link between mental and physical health burden[5]. Chronic pain is the top reason for GP visits. And the multiple co-morbidities of an aging population further complicate the care system. Increasing evidence suggests that infections and microbiota also play a role in non-communicable and chronic diseases.

In addition to this, the management of **infectious diseases**, as well as many surgeries, is becoming more and more problematic. Infections caused by resistant bacteria kill 33,000 European patients annually; anti-microbial resistance costs the European Union around €1.5 billion per year in healthcare costs and productivity losses. On top of this known problem, newly-emerging viral infections could become devastating if not handled effectively and in good time. Climate change may worsen this problem by increasing the threat from vector-borne, food-borne and water-borne diseases, meaning that a one-health approach is necessary.

The disease burden and general health challenges are growing. Citizens are demanding high-quality healthcare based on a patient-centric approach. At the same time, European healthcare

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1. http://www.euro.who.int/en/data-and-evidence/news/news/2016/09/what-is-the-burden-of-disease-in-the-region
2. https://www.alzheimer-europe.org/Research/European-Collaboration-on-Dementia/Cost-of-dementia/Prognosis-to-2030
3. *osteoporosis costs EUR 37 billion in Europe, osteoarthritis costs 1 to 2,5% of total GDP in western countries*
4. https://ec.europa.eu/health/amr/sites/amr/files/amr_factsheet_en.pdf

[2] https://ec.europa.eu/commission/sites/beta-political/files/political-guidelines-next-commission_en.pdf; https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides_en.pdf

[3] https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death

[4] *https://jnnp.bmj.com/content/76/suppl_5/v2*

[5] *Firth, Joseph, Najma Siddiqi, Ai Koyanagi, Dan Siskind, Simon Rosenbaum, Cherrie Galletly, Stephanie Allan et al. "The Lancet Psychiatry Commission: a blueprint for protecting physical health in people with mental illness." The Lancet Psychiatry 6, no. 8 (2019): 675-712.*

systems face other **cost pressures** from insufficient effectiveness and efficiency in the delivery and fiscal pressures. Addressing the challenges of this perfect storm creates an urgent need for increased innovation and cross-sectorial collaboration.

New science and technologies have yet to gain traction

In healthcare many new scientific and technological advancements are either not yet used or underused because of slow adoption, data analytics failing to reach its full potential, and interdisciplinary barriers in medical science.

These new advances have transformative potential when implemented properly. In recent years precision therapies have also emerged. Integrating these new products and services into medical practice remains challenging. The main barriers include siloed approaches, different sets of standards and evidentiary requirements, limited translation of science into products and services, and reimbursement that focuses on disease management rather than health.

Access to (Big) Data is often seen as a critical enabler to transforming healthcare. But its value remains largely untapped due to poor data quality, missing skills and know-how, low interoperability and interconnectivity, inconsistent standards, inefficient implementation strategies, and the cost of analysis. Due to the shared competence on public health between the EU and the Member States, actors within the healthcare sector face a fragmented policy landscape. While the EU has benefited from a strengthened framework on data protection, uncertainties remain on e.g. on secondary use of health data and de-identification creating additional complexity. For researchers the biggest challenge is access to meaningful data at large scale.

Medical science is becoming increasingly interdisciplinary, making multiple perspectives increasingly important, from bio-health, bioinformatics, biomechanics and biochemistry to chemistry, physics, mathematics, biology, micro- and nanotechnologies, data science as well as social and behavioural sciences. Further leveraging the synergies between “big data” and digital tools, offers a great opportunity to analyse multiple pathological conditions for many complex diseases, pointing the way towards more precise prevention, diagnosis, treatment and personalised care. This will require co-operation not just within, but across sectors.

The cross-sector public-private partnership (PPP) enables integrated and personalised healthcare

Innovations to tackle the health challenges are within reach. But it takes too much time for health innovations to reach patients, and diffusion of innovation is not uniform across countries and throughout the EU. To facilitate the uptake of health innovation and accelerate the speed with which it can transform European healthcare we propose a PPP that drives cross-sector and integrated innovation. While the need to enhanced cross-sector collaboration and integration of technologies is widely shared by the scientific and health communities, this PPP will create a platform to move from intentions to real world implementation.

For the PPP**,** the **overall goal is to accelerate the development of safer and more effective healthcare interventions that respond to unmet public health needs, and that can be taken up by healthcare systems.** It will enable fast delivery of the most pertinent (personalised and precise) and safest innovations to citizens, patients, healthcare professionals and care givers, improving health outcomes, while enhancing the competitiveness of the health industry and sustainability of health systems. A competitive healthcare industry in Europe means also jobs, value and impact on the local/national economy.

The partnership will address cost-effective health promotion, disease interception, prevention, diagnosis, and management through:

1. ***De Novo* data generation** along the whole R&D value chain: generating high-quality, harmonised, reliable, annotated, interoperable data that can be shared, e.g., for larger integration, interoperability and/or where economies of scale are needed. For instance, a shift in focus to prevention of disease and diagnosis of pre-disease states, will require data on very large cohorts of healthy people that are not identified as high-risk.
2. **Integration of technologies and know-how to create and deliver better and safer products and ancillary services**: each individual company would leverage new science and technologies such as artificial intelligence, connected health systems, and new knowledge of genomics, micro-system- and nanotechnologies, understanding of the biology of diseases to develop new products and services for disease prevention, prediction, interception, intervention and management. This integration also includes activities to optimise the innovation pathways both within and across the sectors in terms of common standards, models, platforms, methodologies, etc
3. **Integration of these products and ancillary services to create innovative health care solutions**: companies would combine the existing and/or new innovations across the sectors to create solutions, and enable their integration them along the patient care pathway.
4. **Integration of clinical, community, social and informal care workflows**: development of solutions to support improved operational care workflows in clinical or community setting.
5. **Proposing operational and business models for innovations involving different health industry sectors**: as companies move beyond single products to offer solutions, integrating these solutions into the entire healthcare system will require different operational models, from regulatory sciences to definition of outcomes and co-development pathways. The ultimate end might be to link the development cycle of pharma, diagnostic and medical device and digital companies.

In order to achieve these goals for the Partnership, **five concrete areas of actions across sectors are outlined in chapter 2.**

1. **Area of action 1:** Harness advances and synergies in genetics, biology and technology for less invasive, more precise and effective prevention, diagnosis, treatment and care
2. **Area of action 2:** Develop patient-centric, integrated products and services along the entire healthcare continuum
3. **Area of action 3:** Apply “Big Data” and advanced analytics / artificial intelligence (AA/AI) to enable research, development and business opportunities for integrated healthcare approaches
4. **Area of action 4:** Empower citizens and patients to engage with, manage and improve their health
5. **Area of action 5:** Strengthen Value-Based Decision making in Health and Social care systems

Industry's contribution will be a combination of expertise (spanning the fields of regulation, technology, science, cybersecurity, quality assurance and market access), development programmes, structured high-quality data and evidence platforms, equipment, solutions and prototypes. And by bringing together industry players from the entire value chain (companies of all sizes, including SMEs, from all relevant sectors) with relevant academics, research organisations, regulators, procurers, payers, healthcare authorities, healthcare professionals – and carers, patients and citizens at large – the PPP will:

1. **Accelerate product/service innovation**: it will deliver solutions in the form of tools, data, platforms, technologies and processes to create new products and ancillary services (and new combinations) to predict, prevent, intercept, diagnose and manage diseases and aid recovery more efficiently
2. **Contribute to creating learning health systems**: it will demonstrate the feasibility of public and private data interoperability and of methodologies that better predict healthcare systems' and patients' needs, make systems more efficient, and assess the value of new care interventions
3. **Optimise health journeys**: it will deliver data infrastructure, access interfaces, analytical and visualisation methods that optimise the health journey, from health promotion to disease prevention and early diagnosis to disease and health management, including decision-making processes for patients and healthcare professionals and caregivers
4. **De-risk innovation**: incentivise R&I through the development of tools and methods in regulatory science and health technology assessment including health economic evaluation adapted to the evaluation of integrated healthcare interventions
5. **Strengthen competitiveness**: it will make it easier for European industry to thrive on a world stage and incentivise knowledge transfer into European SMEs and within the European academic ecosystem
6. **Improve health**: ultimately, in the longer term, the PPP will contribute to better health outcomes across the EU.

Value of a public-private partnership: The seamless and widespread translation of new and existing knowledge into innovative, scalable and effective products, strategies, interventions and services will be vital and will require long term and coordinated support for co-operation. The life sciences, medical, digital health and bio-technology industries operate in a highly-regulated environment where innovation is research-intensive. With new developments in technology and healthcare delivery, technical, regulatory and ethical complexities are increasing.

Horizon Europe offers us the opportunity to create a unique platform that does not exist anywhere else, a multi-sector partnership for health innovation to break the silos between different industries first, and between industry and their respective stakeholders second. Joint undertakings such as IMI and ECSEL demonstrated that some of the most difficult questions related to safety, efficacy and effectiveness, or pioneering and de-risking new research pathways can only be addressed when public and private sectors share their assets and collective intelligence. Having successfully pushed the boundaries of precompetitive research within individual sectors in Joint Undertakings under Horizon 2020, we are ready to do it in a multi-sector setting to maintain Europe at the forefront of innovative solutions for medical and health sustainable systems.

This paradigm shift requires a neutral broker to happen. Moreover, public-private collaboration is necessary to ensure a balance between public (healthcare systems, payers and patients) and private interests in this process. At the same time, improved understanding of healthcare needs will lower the risk for companies and encourage private investment in healthcare research & innovation in Europe.

The initiatives under this partnership will contribute to the overarching priorities of the European Commission, including the Europe's Beating Cancer Plan and the research and innovation mission on cancer[1].

Member state and stakeholder engagement: Aligned with the priorities of the European Research Area (ERA), the PPP will foster more-effective national research systems, increase access to and transfer of scientific knowledge and allow for optimal transnational cooperation on research. Effective engagement in a cross-sectorial collaboration requires mobilising a very broad range of companies and other stakeholders, of expertise, of knowledge and resources, all currently dispersed in Europe. No Member State alone would have the legal and financial framework to develop a multi-sectoral collaboration on the scale needed to bring pan-European long-term structural improvement.

Health R&I is increasingly a global endeavour, notably as regards digitalisation and data exchange. Joint action at EU level would foster coordination of stakeholders and would be more effective in reaching the objectives than running multiple smaller-scale initiatives at national level. Most health-related companies operate EU-wide and the involved sectors are governed by EU-wide legal frameworks.

While the areas of action listed in this SRA set the scientific standards and objectives that the PPP aims to achieve, the operational structure is also planned to collect key stakeholders' input into the scientific planning process systematically in a way that is open, transparent and sustainable.

[1] https://ec.europa.eu/commission/sites/beta-political/files/political-guidelines-next-commission_en.pdf

Chapter 2: Strategic areas to contribute to integrated healthcare

We have identified five areas of action that will accelerate the delivery and uptake of innovative solutions while strengthening the sustainability of healthcare systems and competitiveness of health industries. These areas are set out in more detail below, and the annex provides illustrations of how these areas of action could address health challenges.

Area of action 1: Harness advances and synergies in genetics, biology and technology for less invasive, more precise and effective prevention, diagnosis, treatment and care

Challenge: the full power of new advances in medicine, science and technology has not yet been captured, partly because of interdisciplinary boundaries and barriers to diffusion. We need to accelerate the convergence of multi-disciplinary sciences and leverage synergies of enabling technologies, data science, digital methods and knowledge of biology to promote health, to predict and prevent diseases and comorbidities early, diagnose them rapidly, intercept them before "breakout" and develop innovative health technologies such as advanced therapy medicinal products (ATMPs) or combined interventions for treatment and care.

Scope: our aim is to support more effective disease prevention, interception and management and accelerate delivery of safer and more precise diagnostics and treatment interventions through the continuum of care. The partnership will aim to enhance disease understanding and enable the development of e.g. novel disease targets, health technologies including diagnostics, device-based therapeutics, etc. The scope will also cover innovation in manufacturing (including green manufacturing and the overall environmental footprint[1][2]) and products and services delivery. The synergies to be captured stretch across sectors but there will also be gains from sector-specific optimisation of health research approaches).

Potential outputs/deliverables: We plan to increase our understanding of human disease biology by creating new tools and technologies and using them to interrogate potential mechanisms highlighted by genetic studies and then testing these approaches in clinical studies with appropriate biomarkers.

We will leverage technologies to improve existing innovations in a number of areas. We will build a knowledge base and tools to better help people stay healthy, better understand individual patients' status for personalised prevention and treatments or vaccines for prevention and treatment of diseases.

We plan to be better prepared for infectious disease outbreaks, with ultra-rapid tools, real-time dashboards tracking the spread of the outbreaks and platforms for accelerated vaccine development, to deliver new interventions and provide the most relevant available treatments to patients in good time.

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[1] https://ec.europa.eu/growth/tools-databases/dem/watify/boosting/news/green-manufacturing—-solution-reducing-production-waste

[2] https://www.ec.europa.eu/environment/water/water-dangersub/pdf/strategic_approach_pharmaceuticals_env.PDF

We aim to understand the interrelationship between infections, microbiota and non-communicable diseases better and develop integrated tools that take this into account.
We aim to develop precision medicine solutions with fast diagnostic tools for targeted treatments, for example, using wearable devices to monitor critical parameters *in-vivo* or *in-vitro* allowing better monitoring. Better linking of infectious and chronic diseases will optimise patient outcomes and limit co-morbidities.

We will target and localise therapeutic and preventive effects through minimally-invasive systems and approaches, devices and implants, enabled by micro-nanotechnologies, integrated photonics and microelectronics, including drug delivery in closed-loop systems. Improvement of minimally invasive surgery and interventions could reduce lengths of stay and hospitalisation costs; it could reduce the chances of becoming ill and reduce the need for complex care.

In chronic disease, we plan to develop better methods to help people manage their own health and identify pre-symptomatic individuals for preventive treatment. Cost-effective methods could be used during routine physical examination prior to more extensive evaluations.

For non-communicable diseases, we will develop novel treatment paradigms that range from technology to process: for example, from artificial pancreases and new cancer imaging technologies to multi-disciplinary integrated treatment and behavioural change for obesity, or from refined diagnosis combining AI and fully automated digital predictive models to prevention of osteoporotic bone fractures as well as targeted treatment of osteoarthritis.. These should cover the full range of non-communicable diseases.

We will build predictive models for pathogen emergence and resistance to contribute to the development of improved targeted anti-infective therapy and new vaccines. We will develop, digital tools, including artificial intelligence for appropriate prevention, testing and surveillance of infections.

We will propose novel development, evaluation and delivery pathways (including regulatory and financial considerations) to support diagnostics, vaccines and therapeutics R&D, to encourage continued investment in infectious disease research.

We will develop and test novel clinical trial methodologies supported by regulatory authorities for innovative health interventions and their combinations. This could be tools to improve the design, conduct and analysis of clinical trials.

Innovations in manufacturing may include continuous and additive manufacturing (= 3-D-printing), decentralised manufacturing / supply strategies and further leverage digitalisation and automation on the shop floor including technologies like Augmented Reality / Virtual Reality. The synergies to be captured stretch across sectors but there will also be gains from sector-specific optimisation of clinical research approaches.

Overall, we will aim to explore novel solutions for continuous disease management and monitoring of patients for a more efficient follow-up of treatments, *ex-vivo*, *on-vivo* and *in-vivo*, using the Internet of Things and new sensing approaches.

Expected impact: This area of action will lead to the delivery of innovative products, services and solutions that meet patients' and healthcare systems' needs. These new tools will enable accelerated implementation of healthcare innovation, allow for early interception of disease, deliver new precision and personalised care while balancing and optimising healthcare expenditures based on medical and economic value. This will improve overall well-being.

EXAMPLE: Anti-Microbial Resistance[1]

Problem Statement: Antimicrobial resistance (AMR) remains paradoxically under-addressed. It is caused by misuse and overuse of antibiotics in various settings (community, hospitals, long-term care facilities, farming etc.). Current practices and models require a change of paradigm that only a cross-discipline and cross-sectorial approach can make happen: prevent, diagnose, treat, follow-up with a patient-centered information and data workflow enabling optimum medical management and outcome in a constrained healthcare expenditure context. Management of AMR is transversal to many other diseases (comorbidities) and information on patient status and treatment options must be seen from both a vertical standpoint (now) and over time (pathway). Infectious-disease treatment and management remains empirical due to lack of precise, timely information available for clinicians, with important mortality and morbidity issues arising in the hours or days immediately after infection onset. Overall antibiotic efficacy is decaying with fewer new and last resort molecules available.

Project Description: faster diagnostics for point care testing and triage of patients would enable targeted antimicrobial/antifungal/antiviral treatments. More precise/exhaustive diagnostic tools targeting the host (biomarkers including microbiota characterization) and the infectious micro-organism (identification and susceptibility to antimicrobials) will be deployed. Dataset collected thanks to connectivity and interoperability of systems will allow to detect and analyse type of bacteria in samples, resistance profile and geographical distribution overtime for optimal treatment decision making (antimicrobial stewardship). Precise diagnostic tools would support and enhance patient recruitment in Phase 2/3 clinical studies of novel antimicrobials/antiviral providing multiple benefits. Non-drug-based intervention (antibodies, bacteriophages, others) would be developed for targeted treatment of specific bacterial infections. It would include the development of new antibiotics and alternative – non drug based - treatment options (and their combinations) such as immunotherapy and phagotherapy against gram-negative bacteria. Intravenous delivery tools of antibiotics would be based on personalised drug monitoring for efficient dosing and compliance to treatment of last resort/targeted antibiotherapies

Expected Outcomes:
Reduced uncertainty will lead to improved treatment decision-making, hence better patient outcome. Use of current and future antibiotics would be optimised; a wider range of interventions (including new classes of products) would be available; infection rates and healthcare costs would be reduced, as would the antibiotic resistance rate and emergence against current and new antibiotics.

[1] *General disclaimer: These examples only serve the purpose to illustrate the areas of action outlined in the Strategic Research Agenda. Their inclusion in this document does not mean that they will actually be turned into fully-fledged projects in the future partnership. It also does not exclude other activities in this disease area in other areas of action, as further major challenges need to be addressed.*

Area of action 2: Develop patient-centric, integrated care solutions along the entire healthcare continuum

Challenge: the treatment of diseases often remains siloed into medical disciplines. We need to use a combination of drugs, diagnostics, medical devices and complementary services to provide patient-centred solutions along the care pathway. In parallel, the PPP will develop tools that enable system integration and standards for patient-centric integrated care models.

Scope: our aim is to understand how to achieve an effective continuum of care, by combining and strengthening existing solutions, leveraging real world evidence and centring solutions around the patient. Projects will investigate what solution should be provided to patients and at what time. Integrated products and services could be developed for each given disease. Efforts will be made to support integration both vertical (patient's complete status, behaviour and potential co-morbidities), transversal (across pathways), and territorial (among care providers). A goal is to integrate in vitro/in vivo diagnostics as a crucial element in patient management for early and adapted treatment by novel patient specific effective therapeutic interventions. The right treatment at the right time avoids unnecessary interventions and related costs. To ensure that integrated care solutions meet the needs of users, it is crucial that healthcare professionals, informal carers, patients and citizens are participating in activities under this area of action.

Potential output/deliverables: The PPP will contribute to better integration of tools and services into the health ecosystem. This includes development pathways for the combination of products and integrated solutions for diseases and their comorbidities and for well-being. The PPP will also facilitate guided therapy as well as surgical decision support solutions by acquiring, integrating and analysing pre-/intra-/post-operative patient data and hospital information to enable better treatment choices and decision-making and to improve standards of care with the involvement, input and supervision of the relevant healthcare providers.

Projects will develop products and services to support more efficient operations and workflow, including digital health solutions, data architecture and system engineering, that transform the health system all the way from health promotion to hospital and back to home. These could be tools supporting the management of patients in the emergency or 24-hour monitoring and accompanying tools integrating virtual care and the eICU[1]. Combinations of tools, biosensors, guardian software and related services that monitor and accompany well-being will provide early warning of patient deterioration in a home care environment.

Other potential deliverables are integrated medical and non-medical solutions (health promoting and disease preventing activities) for improved patient outcomes. These will be used to improve guidelines for care.

This area will build on activities from area of action 1, including a better understanding of the causes of global disease (aetiology), and their prevention and cure. In addition, relevant data collection for multi-morbidities (from area of action 3) will be conducted.

As a next step, the PPP will contribute to setting up the environment, infrastructure and will provide evidence and standards for integrated products and services. Potential deliverables include algorithms for continuous disease management, new protocols of care and harmonised clinical algorithms as simulation of models for integrated care solutions (covering integrated

[1] https://eicu-crd.mit.edu/

products, tools and services). Building a new database with possible treatments, or integrating existing ones, could contribute to defining more uniform and efficient disease management pathways. This area of action will investigate possible paths to the scaling up of integrated solutions and new models of population level screening for early intervention (via risk identification and early detection).

Expected impact: This area of action will contribute to breaking silos with a view to providing holistic, patient-centred continuous care even before diseases occur, promoting health and well-being. This will improve health system efficiency by generating savings, and by reducing inefficiencies due to boundaries between medical disciplines. The changes in behaviour that it drives will also be a necessary foundation for area of action 4.

EXAMPLE: Cardiovascular disease

Problem Statement: Cardiovascular diseases (CVDs) remain the largest single cause of death (26.6%) in Europe and account for 11.8% of the total disease burden[1]. Of these deaths, 57% have been attributed to risk factors such as smoking, poor diet (including low fruit and vegetable intake), low rates of exercise, high blood pressure and blood glucose, obesity and high cholesterol. Low birth weight is associated with increased cardiovascular (CV) mortality in adult life.

Project Description: the project will develop early life CV disease risk stratification by combining perinatal, epidemiological, imaging data and genetic predisposition from large cohorts. We would establish genetic determinants of CV remodelling after adverse fetal environment, by integrating several large birth cohorts and biobanks. We would describe quantitative imaging biomarkers that predict CV remodelling and provide missing links in the transition from fetal changes to adult disease. We would improve understanding of the independent and combined effect of fetal programming on long-term CV health. We would develop and validate an integrated clinical tool combining perinatal, genetic and imaging data, with an algorithm for the prediction of CV risk from the earliest stages of life onwards through adulthood.

Expected Outcomes: early-life risk stratification could prevent thousands of deaths, since early lifestyle interventions can revert CV changes with proven impact on future health. Avoiding and delaying CV events has a major economic impact.

[1] *Murray et al. Lancet 2013*

Area of action 3: Apply "Big Data" and advanced analytics / artificial intelligence (AA/AI) to enable research, development and new types of products and services to support integrated healthcare approaches

Challenge: the value of data in healthcare remains largely untapped. In the first place, data are hard to gather: HCPs are too busy to record them and see no direct benefit; amplified by poor interoperability of medical equipment, heterogenous hospital data systems, patients are often reluctant to give up data they "own" that have an economic value. Even where data are gathered there are challenges of variable data quality, a lack of the right skills to handle the data, poor interoperability and interconnectivity, conflicting or unclear standards, inefficient data strategies, and the high cost of analysis.
While the EU has benefited from a strengthened framework on data protection, uncertainties remain on e.g. on secondary use of health data and de-identification creating additional complexity. For researchers the biggest challenge is access to meaningful data at large scale.

Scope: our aim is to strengthen and reinforce some promising trends and developments that are already underway. These include EU initiatives to standardise health data around common data formats and standards, including linking genomic databases across borders and the development of an Electronic Health Record Exchange Format[1] ("EHRxF"). We intend to make full use of data and advanced analytics, algorithms and digital tools supported by high-quality, interoperable data, including Artificial Intelligence to better promote health, predict, diagnose and treat the disease, and improve healthcare processes and care flows.

Projects will promote the pooling, integration and sharing of high-quality, harmonised, interoperable data that can be shared (either existing or generated *de novo*) on which Artificial Intelligence analyses can be carried out.

Accountability to individuals and society will be assured through the adoption of core principles of good data governance consistent with GDPR and an ethical approach to AI in line with the *Ethics Guidelines for Trustworthy AI*[2] released in April 2019 by the EC's High-Level Expert Group on Artificial Intelligence, encouraging patients' consent to authorise the use of their data. Cybersecurity and data protection (including the use of blockchain and similar processes) will be investigated to support the trustworthy use of healthcare data.

The keys to unlock patient/citizen data may include a publicly-managed electronic health record system, like the EHRxF, that builds on the doctor-patient relationship; and collaboration between industry and public health systems to identify mechanisms for using data to further wider goals.

Potential output/deliverables:
We will define a roadmap and aim to implement data standards that leverage the learnings from other big consortia on data. With that in place we will develop tools and technics for data extraction, data sharing, data interpretation and data reusability; contribute to a definition of quality and quantity of data to ensure representativeness and set standards for how data are captured, processed, transferred, stored, shared and re-used. We will set common standards for interconnectivity and interoperability of medical device *and in*-vitro diagnostics that need to be adopted.

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[1] *Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019H0243*
[2] *Ethics Guidelines for Trustworthy AI - https://ec.europa.eu/newsroom/dae/document.cfm?doc_id=60419*

At ecosystem level, we will contribute to the design of an incentive system for buyers/procurers of health technologies compliant with relevant data and quality standards. This will facilitate automated measurements that enhance the quality of reporting clinically significant findings across Member States. We will also facilitate the successful deployment of the IT infrastructure necessary within healthcare for AI and machine learning. This includes training programmes on AI for medical researchers and a learning environment. We will promote advanced analytics/artificial intelligence along the continuum of care pathways and the health industry value chain to deliver patient-centric integrated care and citizen-centred health promotion. One output could be a sharable database for real-world patient data, and clinical and preclinical data from pharma companies, device companies and academia research institutes.

The PPP will investigate methodologies for Competent Authorities to make full use of the potential of real-world data from various sources and multiple stakeholders to identify patterns and signals (using Big Data analytics, Artificial Intelligence, Robotic Process Automation, machine learning) in order to improve the safety of medical devices or drug-device combination throughout the product lifecycle. The availability of such methods will also allow for a better understanding of the factors impacting clinical effectiveness and safety of medical devices (including patient's characteristics, comorbidities, lifestyles, association with other medical products or health interventions), and contribute to improved monitoring of patients' health as well as informed clinical decision-making. These activities need to be conducted in collaboration with the Competent Authorities in charge of vigilance and market surveillance activities.

We will aim to lead a dialogue with regulators, aiming for a methodology for patient stratification leveraging advanced analytics or biomedical models for artificial intelligence-based automation, visualisation and decision support, taking data, context and population information into consideration.

Expected impact: This area of action is expected to unlock the value of data in integrating technologies and know-how to create better knowledge, products and integrated solutions. Overall, this would promote Europe's leadership in the digital space. Harmonised interoperable data and widely implemented advanced analytics/artificial intelligence will contribute to the integration of workflows along the care continuum. This should lead to personalised interventions, shorter development cycles, improved quality assurance, shorter times-to-market, optimisation of research/development and manufacturing processes. More accurate and/or rapid detection, diagnosis and treatment will result in improved outcomes for patients. Healthcare providers and professionals will benefit from Artificial Intelligence to support the decision-making. Not only can it increase the accuracy of diagnosis and efficacy of treatment, but also improve efficiency of their workflows by having information readily and quickly available, reducing greatly the throughput and lead times. It will be accompanied by education programmes to facilitate the uptake of AI technologies by healthcare professionals.

EXAMPLE: Neuroscience

Problem Statement: Brain disorders affect one in three people during their lifetime – currently 165 million Europeans. They cost around EUR 800 billion every year. This cost exceeds that of CVD, cancer and diabetes combined. As the population in Europe ages, these numbers are increasing. WHO concluded that brain disorders account for 35% of the burden of all diseases in Europe and are predicted to become the major medical need of the 21st century (source: European Brain Council). A large number of clinical databases exist in the CNS space not least those generated by previous IMI initiatives, US funded programmes, and those within industry. These data bases all use different curation architectures, data standards and have disparate rules on access. If these could be harmonized, then the true benefits of advanced analytics

and AI could be brought together to probe these disorders without bias with respect to minority groups, women and children.

Project Description: A collaboration between existing EU and Member States funded projects facilitated by a consortium dedicated purely to this task would build a powerful engine for digital research. This would be further powered if transatlantic collaboration with initiatives such as “Data Commons” could be agreed. Academics, industry, charitable institutions, patient advocacy groups would thus form a consortium to agree the common structure and standardized formats. These would then be put in place and populated from existing datasets while also leveraging new data funded from projects on the understanding that this common structure would be implement a priori. Finally, discussion with regulators would be initiated. For deployment of databases in research into improved diagnosis and/or therapy using artificial intelligence technology, esp. the newest method of (trained) deep learning, it is essential that clinical databases contain accurate references (e.g. annotated lesions, segmented tissue structures, etc.). Translation of developed AI technology into clinical practice would additionally greatly benefit from agreed performance thresholds.

Expected Outcomes: The data repository created and curated, would be available for both prospective and retrospective analysis, to allow researchers access to much larger, searchable data sets than previously possible. This maximizes the use of existing clinical research and well as sets a standard for data sharing going forward. This will allow optimized clinical, value-based outcomes as well as a platform to advise health policy at a European level.

Area of action 4: Engaging citizens and patients to manage and improve their health

Challenge: although the importance of empowering patients and carers is widely acknowledged, support for this process remains patchy. Citizens expect to play an active and stronger role in their own individual health promotion, disease prevention, interception, diagnosis and treatment/management. At the same time, this also represents a huge opportunity for the healthcare system at a collective level. The WHO has defined health as "the state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" and empowerment as "a process through which people gain greater control over decisions and actions affecting their health", which is both an individual and a community process. Four components aligned with the WHO Global Strategy on Digital Health[1] are fundamental: 1) understanding by the patient of his/her role; 2) acquisition by patients of sufficient knowledge to be able to engage with their healthcare provider and where possible self-manage their treatment and care; 3) patient skills; and 4) the presence of a facilitating environment;. In this area of action tools and knowledge can be built to empower patients to engage proactively in research and shape their own health and healthcare journey.

Scope: The PPP will concentrate on involving citizens and patients early in the process, i.e., co-design, develop and test tools and means to engage in research and innovation activities as well as to enable more efficient self-management of disease and health. We will ensure that patients' needs are taken into account when health solutions are designed and evaluated, which will ultimately increase the quality of healthcare and adherence to treatment and vaccination. This will also include tools to enable improved communication and interactions between the patients, healthcare professionals and informal carers.

Potential output/deliverables: Some possible outputs will raise patients' understanding and knowledge: educational and accompanying programmes for citizens and patients on their role and contribution to the health promotion and healing process, and their involvement in clinical trials (ensuring a gender perspective, in order to address gender-based physiological differences in patients); digital health literacy education programmes, including the topic of the role and value of health innovation; virtual patient communities for self-education and mutual help, including for elderly patients, and education to help citizens understand the value of vaccination. The specific needs of children and their carers will be considered as well.

Some outputs will build a facilitating environment: methods for integration of citizen/patient-generated information and insight in regulatory decisions and process across sectors; apps, tools, devices, and activities to engage citizens/patients in health promotion, disease prevention and management, compliance and adherence.

Other outputs will build the case for empowerment: a demonstrated impact of patient and citizen education on prudent antibiotics use; demonstrated impact of citizen empowerment through non-medical interventions and lifestyle change (nutrition, physical activity, body-mind interventions, stress reduction) on prevention and treatment of infectious and non-communicable diseases, including vaccination.

Expected impact: empowered citizens and patients have a better understanding of their health condition and the treatment effects on their body. Empowerment puts them in a stronger position to participate in decisions with healthcare professionals and make informed choices about prevention, including vaccination, and treatment. They become partners of industry and

[1] https://www.who.int/news-room/detail/17-04-2019-who-releases-first-guideline-on-digital-health-interventions

healthcare systems and no longer end-users only. It contributes to a better understanding of whether and how they might need to adjust their lifestyles and take responsibility for their health, based on increased use of available quantitative and qualitative information

Collaborating with citizens and patients is already leading to better trials, better engagement, better communication throughout the entire life cycle of medicines better prevention and ultimately better patient outcomes. Ultimately, it has the potential to generate healthcare cost savings, because empowered citizens and patients are more inclined to take health-promoting and preventive measures, including vaccination, and seek earlier diagnosis.[1]

EXAMPLE: Prostate cancer

Problem Statement: in 2015, 75.3 thousand men died from prostate cancer in the EU-28, equivalent to 5.7 % of all deaths from cancer and 1.4 % of the total number of deaths from any cause[2]. Understanding and early diagnosis of the disease remains a major challenge, including the identification of early and apposite biomarkers. There is also a need to reduce overdiagnosis and overtreatment of indolent prostate tumours that are detected by inadequate screening. On the other hand, aggressive disease needs to be diagnosed and treated on time. Patients may have a choice of treatments, including surgery, radiotherapy, brachytherapy, hormone therapy, chemotherapy, and "waiting". The most common source of patient dissatisfaction is not being properly informed about their (risk of having a) disease and the options for treating it.

Project Description: a decision support system tool for the self-management of prostate cancer by citizens. This will be a web-based dashboard that integrates various tools for personalised risk assessment with supports in therapy selection and monitoring of indolent disease. These tools are combined with balanced information on the disease and lifestyle. The decision-support system for self-management of prostate cancer to citizens will be evaluated in multiple European countries and will be widely disseminated throughout Europe to over x million citizens. The web-based support system for citizens will facilitate decision-making for the following questions: should I test for prostate cancer? should I have a biopsy? which therapy should I choose for the treatment of my prostate tumour?

Expected Outcomes: Citizens fully involved in their personal prostate cancer therapy selections. An individualised decision support system for self-management of prostate cancer, thanks to experience acquired by diagnostics, medical device, pharmaceutical companies, health professionals and patients involved in diagnosis, treatment and living with prostate cancer

[1] http://www.eu-patient.eu/campaign/PatientsprescribE/
[2] Eurostat. (2019). https://ec.europa.eu/eurostat/statistics-explained/pdfscache/39738.pdf

Area of action 5: Strengthening Value-Based Decision making in Health and Social care systems

Challenge: The incremental effectiveness and cost-effectiveness of new technologies are in many countries evaluated through Health Technology Assessment used for different purposes including informing reimbursement and guidelines for pharmaceutical innovation across Europe and selective medical devices in specific countries. Methodological advancements including on the use of real-world evidence are developed by several EU-funded initiatives[1] and cross-border collaborations such as EUnetHTA[2].

Looking beyond individual technologies, to meet the pressure of an ageing population which creates increasing demands on health systems, many health policy makers are aiming to better understand how to allocate healthcare budgets in order to maximise the outcomes created for patients and the benefits for caregivers, healthcare professionals, providers and societies while obtaining timely and cost-effective delivery of quality care of societal and economic value. However, the tools to enable this change are still under-developed and only deployed in part in health systems. More importantly, the health outcome and well-being of a patient, or the health status on a population level, is affected by several inter-connected parts of the health and social care system including screening, diagnoses, prevention, self-, home-, community-, hospital care coordination of healthcare services and patient pathway including disease management programs and the use of medicines and medical technologies. In particular, the effect of different health and social care interventions on patient-relevant health outcomes and their well-being is still poorly understood in many parts of health and social care, and there is an insufficient deployment of measurement tools (including Patient Reported Outcome Measurements (PROMs), transparency of outcomes data and use of this data in decision-making at all levels. The nature of this challenge was recognized by the OECD health ministers in 2017, when they stated that:

> *"We discussed policies that have successfully helped tackle low-value interventions and free resources for investment in the most effective health activities, and how to remove barriers to successful health reform./…/ We expressed our concern for evidence showing that a significant fraction of health spending does not actually improve patient health./…/ We need to invest in measures that will help us assess whether our health systems deliver what matters most to people. /…/ Measuring how care affects those outcomes that matter most to people and linking those with information already collected by the OECD, such as on expenditure, resources, safety and effectiveness of health care, will help us gain new knowledge on how to improve lives for all."*[3]

To meet the mounting pressure, the life science industry is also evolving in its proposition. Not only technological innovation is offered but also associated services, integrated within a given healthcare setting and across silos. For these new types of solutions, methodologies and tools are needed for the evaluation and rewarding of the value, integrating the perspectives of various actors of the health care system (patients and citizens, health care professionals, payers, providers and industry) , with the goal of better defining value-based decision making and supporting its implementation in health systems.

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[1] *For example research projects funded under the Horizon 2020 Framework Programme such as HTx, COMED, IMPACT-HTA, PECUNIA, MIDAS, BigO, IASIS, PULSE, CrowdHEALTH, EVOTION, Bigmedylitics*
[2] *https://www.eunethta.eu/*
[3] *OECD Health Ministerial Statement - https://www.oecd.org/health/ministerial/ministerial-statement-2017.pdf*

However, implementing a comprehensive view of value, which e.g. includes health outcomes for patients and benefits for health systems and societies, comes with practical challenges, including:

- Few health systems are able to accurately capture the aggregated outcomes and cost of care throughout the entire patient pathway, and appropriately reward both the industry for innovative health solutions and healthcare providers for providing quality care to patients;
- Siloed budgets do not optimize financial and human resources allocation throughout the patient pathway;
- Tools and methods to measure, and reward health care actors for quality health & care supply and provision based on Real World Data are needed.

Scope: The PPP aims to facilitate the transition to more value-based approaches in health systems, centred around outcomes that are relevant for patients, in line with the vision outlined in the OECD Ministerial Statement, by developing solutions in a multi-stakeholder context. Public-private collaboration is necessary to achieve real progress in this area, as the industry brings expertise on value-assessment, and the related evidence generation, relating to their products and services, but the perspective of public sector actors (including health authorities, HTA bodies, payers, healthcare professionals, and patients) are needed to confirm how they perceive value and the feasibility of implementing new value-based approaches (including financing models) in different parts of healthcare. Furthermore, the evidence generation would primarily build on data sources governed by health systems and payers (including registries, EHR systems and claims databases), but also from patients (patient-reported outcomes data) which would require partnership with these actors to be successful.

The PPP will integrate the perspectives of all key healthcare system actors (patients, carers, healthcare providers and professionals, industry and payers) into a modular value framework which could be adapted to reflect national and local priorities and contexts, centred around patient-relevant health outcomes and total cost of care delivery, but also including broader values of health and social care systems and societies as appropriate.

By operating in a multi-stakeholder/ multidisciplinary setting, the PPP will contribute to reach a mutually accepted definition of value-based approach, which could support national relevant authorities to assess and reward the value of integrated healthcare solutions (medicines, medical devices and technologies, in-vitro, imaging and digital diagnostics, digital solutions and AI) and/or integrated services along the health care pathway in real clinical practice (and the contribution of single elements of those integrated health interventions, e.g. contribution of early diagnostic information to quality care and outcomes). Tools and methodologies developed will for example enable variation analysis (e.g. across pathways or providers) and value-assessments of integrated healthcare interventions (including products and services) and thereby also support the implementation of deliverables from area of action 2 by developing the framework necessary to assess the value of these deliverables, and demonstrate how they can be implemented as value-based business models. The PPP will build on existing tools1 for measuring patient health outcomes and healthcare and societal costs where available, and as necessary develop new tools to fill gaps.

[1] *Such as Patient-Reported Indicators Surveys (PaRIS) to benchmark outcomes and experiences of health care that matter to people and focusing on both Patient-Reported Experience Measures (PREMS) and Patient-Reported Outcome Measures (PROMS). MORE*

The PPP will also establish pilot projects to demonstrate impact in specific settings.

Potential output/deliverables: The main objectives of the PPP will include:

- Developing a multi-stakeholder view on the different core elements of value in healthcare delivery and guidance on how they can be adapted to a local context
- Developing tools, methodologies and metrics for assessing the different elements of value delivered by healthcare interventions and supporting the development of value driven access models;
- Developing tools and methodologies, and as appropriate support actions to align all stakeholders, to enable value-based decision-making at at different levels of the health system - including patient care level, provider level and system level (including building out communities of practice, value-based procurement and value-based financing);
- Establishing and investing in partnerships and pilots to demonstrate the impact of developed tools and methodologies and accelerate change.

Examples of specific deliverables which would contribute to these objectives include:

- Methodological models to assess the value of integrated healthcare solutions and/or integrated services along the health care pathway in real clinical practice;
- Guidance on which data points (including on patient-relevant outcomes, process data and costing data) are needed to assess the different components of the value framework in different care settings;
- Methodologies to analyse and assess these data sets in order to conduct value assessments;
- Methodologies to analyse and assess outcomes data (e.g. for variation analysis), including tools for risk adjustment to facilitate trust, comparability and actionability of the data;
- Methodologies and technical solutions for collecting outcomes data needed for value-based models (including through digital tools) and their integration into national health information systems;
- Tool-kit for the use of outcomes data in value-based decision-making at different levels of the health system (including individual treatment decisions, quality improvement in a provider setting, public transparency and patient choice of provider, patient pathway design, outcomes-based payment models (for providers, services or products), and resource allocation on a system level;
- Early value assessment models to define the opportunity of economic and outcomes gains avoiding low value care;
- Modelling and piloting of value-based business models (including value and outcomes-based contracting, integrated financing and payment schemes across care pathways (including health care provision and innovation procurement);
- Modelling on how moving towards payments rewarding the value offered in healthcare could affect financial risks and rewards for different healthcare actors (including payers, providers and industry) in different scenarios;
- Demonstration projects showcasing how implementation of these tools and methodologies can improve patient outcomes and Return of Investment (RoI) of healthcare expenditure;
- Tools for education of patients, healthcare professionals and healthcare managers, and for sharing of best practice.

Expected impact: The PPP will contribute to the development and implementation of value-based methodological approaches in Europe, thereby helping health systems in Europe become more patient-centred and long-term sustainable, as well as contributing to the EU level goals of effectiveness, accessibility and resilience. The PPP would improve existing tools or develop new ones for health systems decision makers to better inform resource allocation, evaluate patient pathway design and integrated care solutions in terms of impact on patient and population health and value for money.

The area of action would furthermore help the implementation of innovative, and integrated products and services delivering clear benefits to health actors including patients, providers and payers. This would in turn allow the EU to remain a preferred area for the health industry to bring innovation to market, with predictable and consistent RoI for the value created and will contribute to improved access to innovation for EU citizens. The integrated approach to value would enable business models also for prevention and disease interception, releasing resources in other parts of the health system, and inform disinvestment in low-value care. Collaboration with existing EU-funded initiatives in the field of HTA would be undertaken as relevant, since the developed tools and methodologies could also inform future development of HTA models.

The impact will also be a better collaboration between all of the many different healthcare system stakeholders (including citizens and patients, providers, payers, policy and decision makers, the industry) to address the challenges health systems and society are facing. This will imply a widespread understanding of the economic value of investing in healthcare. Already, several health authorities have introduced policies and changed practices driven by a value-based approach. The EU can accelerate this change and foster innovation that will support future economic growth and social cohesion. Lastly, it should lead to better care, and improved lives and wellbeing for citizens and patients.

EXAMPLE: Breast cancer

Problem Statement: breast cancer remains by far the most frequently diagnosed cancer contributing more than 25% of the global new female cancer cases. It is also the first leading cause of female cancer mortality, accounting for 14.7% of cancer deaths. In some countries, breast cancer is the most expensive type: in the Netherlands, it accounted for 15% of cancer costs in 2015 and in Germany, 11% in 2008, higher than any other type of cancer. However, there is a need for improved methodologies for assessing the value of new treatments and technologies for breast cancer across the entire continuum of care integrating the perspectives of the various actors and first of all patients[1].

Project Description: the project will collect evidence on the value of the various interventions (including radio-imaging and radiotherapy, surgery procedures including reconstructive surgery and implants, pharmacological treatments, microbiomic biomarkers) implemented along the care continuum for breast cancer: public education/prevention, screening, diagnosis, staging and risk assessment, treatment, and aftercare and follow-up. Outcomes will be reported both by patients, following the Patient-Reported Indicators Survey (PaRIS), and by healthcare professionals, and payers in x countries.

[1] *ScienceBusiness. (2019). The Life Savers: The value of medical and digital health technology in breast cancer care.* https://sciencebusiness.net/report/life-savers-value-medical-and-digital-health-technology-breast-cancer-care

Expected Outcomes: a proposal for a methodology to assess the value of innovative technologies in the breast cancer care continuum.

Chapter 3: Conclusions

When it comes to the health of its citizens, Europe is facing a unique moment in time. The continent provides some of the best healthcare in the world; it is a leader both in vaccine and drug discovery, in medical technology (medical devices, *in vitro* diagnostics) and in recent years, also in digital health solutions. However, today's fragmented ecosystem confronted with the higher complexity of healthcare innovation makes it harder and harder to sustain this leadership position. It is time to embrace the opportunities from innovations both in biology/medicine and in digital technology, and to reap their benefits along the entire healthcare spectrum. This is one way to put Europe at the forefront of the implementation of the SDGs of the United Nations.

The proposed SRA secures Europe's future competitiveness in a world where technologies are changing rapidly and where solutions need to be brought together from all stakeholders in the value chain. Europe R&I has a long and renowned tradition of collaborative research despite its organisation in EU Member States, which provides a unique set of competence and skills all along the healthcare value chain. The PPP offers a unique opportunity by driving multi-sector collaboration to accelerate the development of citizen-centred health care innovations in areas of clear unmet public health needs.

The partnership will advance science and develop innovative health solutions by sharing expertise, resources and knowledge among academia and industrial players in respecting each other's prerogatives. It would also contribute to bringing innovation to the healthcare systems and to increasing their efficiency.

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

The partnership is likely to contribute to improved health outcomes for European citizens, expressed as more life-years in good health, a lower burden of disease, improved patient experience of care, better diagnoses and more efficient therapies. It is expected to constitute an incentive for industry to invest in unmet public health needs, such as brain disorders and antimicrobial resistance. Moreover, the partnership could contribute to the sustainability of healthcare systems and make innovative health interventions accessible to a broader population.

This is a prize worth seizing. It will benefit patients because they will receive better, more personalised care. All citizens will benefit from new disease prevention methods, including new vaccines. Carers will benefit from integrated pathways that ease the burden on them. Healthcare professionals will be able to deliver streamlined care that addresses their patients' real issues. Companies will get access to new innovative solutions and products from cross-sector collaboration; technology development will be de-risked; their probability of success from research will be improved; innovation that creates value will get appropriate rewards. Academics and SMEs will be able to collaborate more easily. It will be better for payers because they will get better outcomes and better value. It will be better for society, which will benefit from healthier citizens and greater resilience – and sooner or later everyone needs

healthcare. And it will be better for the sustainability of the whole ecosystem – on which all these players depend.

But it is not easy to win: it demands a neutral platform where many sectors respect each other and work together in a coordinated manner with all health and research stakeholders on sectoral and cross-sector activities – a space for everyone to contribute, regardless of size and sector. We strongly believe that Europe cannot afford not to act now.

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

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

EuropaBio: European Associations for Bioindustries, https://www.europabio.org/

MedTech Europe: medical technology industries, from diagnosis to cure. www.medtecheurope.org

Vaccines Europe: https://www.vaccineseurope.eu/