Building the future of health research

Proposal for a European Council for Health Research

A consensus document of the
*H2020 Scientific Panel for Health**

Disclaimer: The opinions expressed in this document are those of the Scientific Panel for Health only and should not be considered as representative of the European Commission's official position.

*The Scientific Panel for Health (SPH) is a science-led expert group based on the provisions of the Horizon 2020 Specific Programme that has been tasked with helping to achieve better health and wellbeing for all. https://ec.europa.eu/programmes/horizon2020/en/h2020-section/scientific-panel-health-sph

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Executive summary

A call for action

Europe leads in many areas of research and has powerful models of cross-border, cross-sectoral, international research cooperation. European research funding has evolved from a handful of programmes to become an important component of the research and innovation landscape in Europe. **The European funding landscape is rich but the framework for health research has limitations, which, if addressed, would better serve health needs.**

The Scientific Panel for Health (SPH) received a mandate under Horizon2020 to 'analyse bottlenecks preventing the achievement of better health and wellbeing for all… and propose solutions'. The SPH is expected to provide a comprehensive view on how to advance biomedical research in support of improving health in Europe, and to formulate recommendations to policy makers. To develop this comprehensive view, the panel of experts conducted a comprehensive participatory process with diverse stakeholders from across Europe. Through workshops and conferences, specific aspects were explored such as the regulatory framework, the next-generation workforce, societal participation and impact of health research.[a]

This process identified **specific needs and opportunities for health research as path to better health**.

1. Health, health care and health research form a unique and interdependent ecosystem. Health care is a national competence but cannot be separated from research. The rising costs in health care can only be managed through research underpinning decisions for implementation.
2. The use of health data creates a wealth of opportunities that are amplified by innovations in the digital space. Yet, this potential is currently underdeveloped and underused.
3. Health research is performed in a complex regulatory framework. Navigating the complexity of regulations in health research requires coordination to meet the needs of society and to facilitate health research to the benefit of the patients.
4. The potential of precision medicine raises expectations for further improvement of disease outcomes and increased quality of care but requires evidence and research into effectiveness and impact on overall health care. Health research at the EU-level can identify and address mechanisms that reduce health inequality.
5. In the present rapid evolution in societal structure, many changes have an impact on health. Meeting health research needs requires input from many disciplines including the social and environmental sciences, humanities and engineering, and this extends to health policy.
6. Health has no borders. Europe faces important public health threats, e.g. infectious disease, crossing borders of human and animal health. Health research needs a global and coordinated vision that is open to the world and takes a holistic 'One Health' approach.
7. Challenges in health require a long-term commitment. Chronic and degenerative disease, mental health, and the growth of co-morbities are examples of major health issues that need a comprehensive and long-term view. The path from discovery to innovation and inplementation is long.
8. Health and health care are pillars of the social structure, and a public and societal responsibility. Public funding must address challenges and needs of high public interest, including areas in which the

[a] https://ec.europa.eu/programmes/horizon2020/en/h2020-section/scientific-panel-health-sph

industry is reluctant to invest if the product does not have an attractive market. Health research therefore needs continued public investment.

9. Health and health care are leading economic sectors. Several studies have documented the impact of research. EU developments in digitalization, open science and the support for creative, discovery science create excellent opportunities for innovation. However, a gap in translation and implementation remains and requires dedicated support.
10. The EU manages only one-tenth of the public research investment but is the major funder of impactful, collaborative research. Excellent EU programs push health research, but are not sufficient. Synergy with strategic initiatives in member states and a new model for impactful collaborations are needed to address the challenges for health.

Proposal for a novel approach to boost health research in Europe

The SPH concluded that Europe must build on its existing achievements by **urgently developing a comprehensive policy for health research**. Defining and aligning common projects across EC directorates, the EU and member states, would realize the implementation of 'health-in-all policies' and step up health research to increase its impact on health improvement. This needs a long-term commitment and **structural measures to ensure implementation**, and could be supported by a European Council for Health Research.

A European Council for Health Research would be the next logical step in building health research for the next era. The EU has gradually expanded its programs resulting in a rich but complex landscape of funding for health research. Members states have taken initiatives towards more collaboration. However, overall funding remains fragmented and not sufficient to respond to the current needs or exploitation of opportunities. A European Council for Health Research would connect several European bodies with national bodies across ministries of health, science and innovation, with representatives of citizens and patients, and with public and private actors. Resource optimization, better synergies with programs and funding of member states, and targeted additional funding, as part of a comprehensive health research strategy, will facilitate faster implementation, increased efficiency and visibility, and, importantly, better health care. The mission of this body is ***to increase the impact of health research to achieve better health and well-being of citizens, thereby creating societal and economic value for Europe and the world.***

A European Council for Health Research should provide guidance, leadership and support for health research in Europe. Therefore, it will

- Create a long-term vision & strategy for health research in an inclusive stake-holders' policy board, science-led and ensuring citizens' engagement at all levels
- Engage member states & EU in joint action to fund health research – across the R&D and health care sector – and build novel partnerships with the private sector, overseen by a science-led translational board
- Provide visibility for European health research and engage with international partner organizations and funders

To achieve maximal societal impact and health gains, the focus will be on participative, people-centered, excellent research, and the path beyond discovery and towards implementation including translational science. Research policies will include societal and economic evaluation of impact. This will close the circle of research, innovation and health care, enabling feedback about opportunities, new discoveries and innovation. The specific needs and opportunities for health will guide priorities, developed with

participation of all stakeholders and emphasizing societal value. A European Council for Health Research will provide the necessary leadership for a mission-driven research strategy.

A European Council for Health Research creates **added value**:

- *For the political leadership in Europe:* a next logical step in a growing program around health – providing scientific leadership and visibility to the program – facilitating intersectoral collaboration – mobilizing additional resources – responding to citizens' primary concern – speaking with one voice for Europe
- *For the health research community:* sustainability for very ambitious approaches and long-term projects, preventing loss of investment in time and resources
- *For funders:* optimizing resources – potential for intensified collaboration & mobility – an instrument for stronger global interactions
- *For society:* enhanced possibility for engagement and participation – benefit through better health and reduction of inequalities
- *For industry:* a platform for participative decision making – potential for novel partnerships & faster path to market

A political dialogue is needed

The proposal for a European Council for Health Research to increase the societal impact of health research and thereby improve health aligns with several resolutions and recommendations at the highest level. Good health and wellbeing is number three of the 2015 Sustainable Development Goals of the United Nations. The World Economic Forum 2016 has emphasized the value in health care as has the High-Level Strategy Group on Industrial Technologies of the European Commission (2017). In the United States, a consensus study report of the National Academies (2017) set out a path for global health, emphasizing the importance of international collaborative efforts, of improving R&D processes and developing digital health. The report of the European Commission's High Level Group on maximizing the impact of the EU R&I Programmes (2017) stressed the importance of a mission-oriented, impact-focused approach to address global challenges, to align EU and national R&I investment and to mobilise and involve citizens.

A European Council for Health Research responds to these recommendations.

The most important voice comes from society. Across the world, citizens are united in citing health as a primary concern. Citizens' health is a core priority for the EU and in the 2017 Eurobarometer, 70% of EU citizens demanded for more EU action in the field of health and social security. Therefore measures to improve health should be high on the agenda.

As stated at the 2017 World Health Summit, health is a political choice. The current dialogue on the future of the EU should include actions to bring health research in Europe to the next level, with inclusive, visible leadership and impactful programs. The road to implementation of a European Council for Health Research requires intense consultation and open exchanges of stakeholders and policymakers, spanning the domains of health and health care, science and innovation, and finances. Those discussions will reveal difficulties but may also identify additional opportunities.

Engaging in this dialogue is urgent and necessary.

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1. Society and stakeholders call for action for health research

Europe leads in many areas of research and has powerful models of cross-border, cross-sectoral, international research cooperation [1]. European research funding has evolved from a handful of programmes to become an important component of the research and innovation landscape in Europe [2]. The funding landscape is rich but has limitations which, if addressed, would better serve health needs. Medical research councils have called for further investment to increase competitiveness of Europe [3].

> *".. to ensure a comprehensive policy and quality of research requires a science-led multi-stakeholders' platform for European transdisciplinary health and biomedical research".*
>
> Lancet, 2016

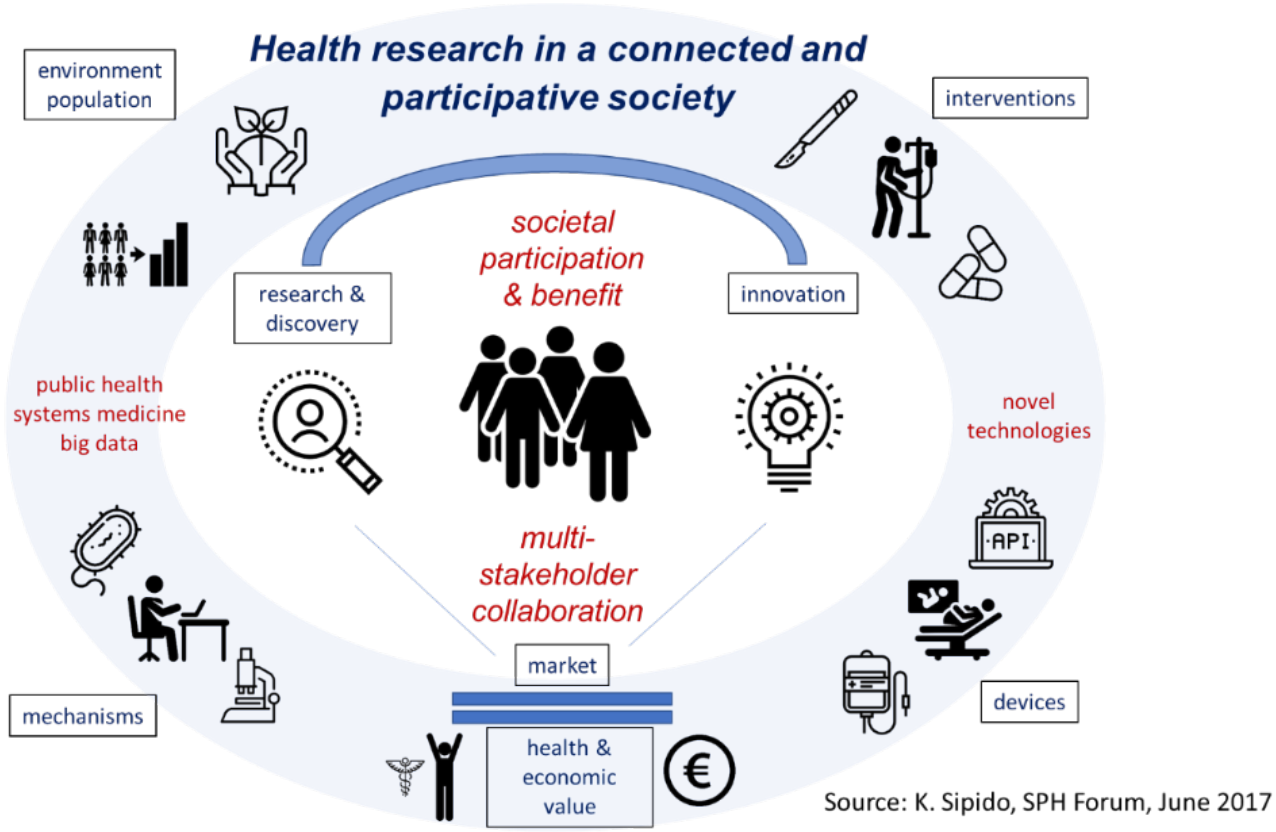
The Scientific Panel for Health (SPH) received a mandate under Horizon2020 (H2020) to 'analyse bottlenecks preventing the achievement of better health and wellbeing for all… and propose solutions'. The SPH is expected to provide a comprehensive view on how to advance biomedical research in support of improving health in Europe, and to formulate recommendations to policy makers. In 2015-2016, the SPH presented a vision paper on a future framework that aims to advance health research through addressing current hurdles and taking advantages of novel opportunities [4]. Through consultation and workshops on several aspects of the vision paper, the SPH interacted with society and stakeholders [5]. The importance of creating societal value and enhancing the impact of health research were stressed A major unanimous conclusion of this process was that Europe urgently needs to develop a comprehensive policy for health research, defining and aligning common projects across EC directorates, the EU and member states, to realize the implementation of 'health-in-all policies' and step up health research to increase its impact on health improvement.

This needs a long-term commitment and structural measures to ensure implementation, which can only be achieved with direct stakeholder involvement. This could be supported by a **European Council for Health Research**. In the present document, the SPH uses the label European Council for Health Research (**EuCHR**) to connect to earlier proposals [6,7], but the emphasis is on the concept and content.

The EuCHR concept was extensively discussed at the Conference on "Health research in a connected and participative society" that took place in Brussels in June 2017 to examine key aspects raised by stakeholders and by the EC [5]. This conference, gathering about 180 participants from 22 EU and EFTA countries, enabled the SPH to launch an open dialogue on the development of a EuCHR and its structure. It was agreed that the aim of the future platform is to create synergies, collating separate goals for research, health care, prevention, global and public health, into a single and inclusive research agenda. As emphasized at the conference (see Figure 1), people should be at the centre of a future framework for health research.

The recent workshop on impact of health research concluded that health gains, reducing inequalities and cost containment of health care are specific aims for impact of health research. The implementation of research results to achieve these impacts requires transformative action. Impact of health research can only be achieved through co-creation and a people-centered approach (Appendix 1).

Figure 1. A future framework for health research puts people at the centre [5]



The EuCHR is the next logical step in building health research for the next era, connecting several European bodies with national bodies across ministries of health, science and innovation, with representatives of citizens and patients, and with public and private actors. Resource optimization, better synergies with programs and funding of member states, and targeted additional funding, as part of a comprehensive health research strategy, will facilitate faster implementation, increased efficiency and visibility, and, importantly, better health care.

The EuCHR will engage society to boost health research through novel models for strategic collaboration, promote a mission-oriented, impact-focused approach to address global challenges, and thereby increase the societal impact of health research. A EuCHR will provide worldwide visibility of European leadership in health research and connect domains such as pollution, agriculture, food, and global and public health. In its goals, the **EuCHR agrees with and responds to the recommendations of the Lamy report** [1,8], released at the time of the conference: 'Adopt a mission-oriented, impact-focused approach to address global challenges' – 'Better align EU and national R&I investment' – 'Mobilise and involve citizens' – 'Capture and better communicate impact'. Considering the European Union's future mission-oriented policy [9], the European Commission's High-Level Strategy Group on Industrial Technologies includes 'European Healthcare Networks – Breakthrough In Disease Prevention And Treatment' in its exemplary missions for EU investment in research and innovation [10].

At the 2017 World Health Summit, the M8 Alliance called on the countries hosting the next G7 and G20 summits and holding the presidencies of key regional organizations to include global health challenges on their agendas and to make the political choices required to ensure the implementation of the 2030 SDG agenda. They noted that "Topics such as health security, antimicrobial resistance and the health impact of climate change, "One Health", "Health in all Policies" reach far beyond the health sector and need the involvement of heads of government and other stakeholders. Interdisciplinary collaboration is the critical factor - all stakeholders from academia, the private sector, civil society and politics have to work together. Governments have to coordinate their activities, support international cooperation and strengthen the World Health Organization (WHO). The Sustainable Development Goals have provided the road map for action." They emphasized that "The world needs strong global health institutions to set norms and standards, respond to outbreaks and to protect and support the most vulnerable" [11].

Despite the advancements in medical knowledge and innocation, it is doubtful that society is gaining its full value from the resources spent on health. There is a great deal of waste due to a convoluted and complex systems where the incentives, interests, strategies, and behaviors of parties engaged in healthcare delivery are misaligned [12]. Rising health care costs are a major threat and require further investment on health promotion and disease prevention [13]. Health measures and patient care should be underpinned by research for innovative solutions and to establish efficacy and efficiency of interventions. As expressed by Commissioner Carlos Moedas at the SPH's conference on "Health research in a connected and participative society" [5] "There are many competing political priorities, so we must all shout about the importance of health research and innovation systems". This is particularly important, because the wellbeing of the people is the direct goal of health research and brings together a wealth of innovations in the humanities, ethics, biology, nutrition, chemistry, physics, ITC, Big Data, economy to urbanisation, sociology, climate and biodiversity. The importance of health research was further underscored by the Portuguese Minister of Health, Manual Heitor, who stated that "specific needs for health research need further investment and require a collective effort in the years to come" [5].

> "*There are many competing political priorities, so we must all shout about the importance of health research and innovation systems*".
>
> Commissioner Carlos Moedas

The following analysis points out why we need to take action and boost health research, the urgency of doing so, and how to build on the strengths of Europe with a new model for collaboration.

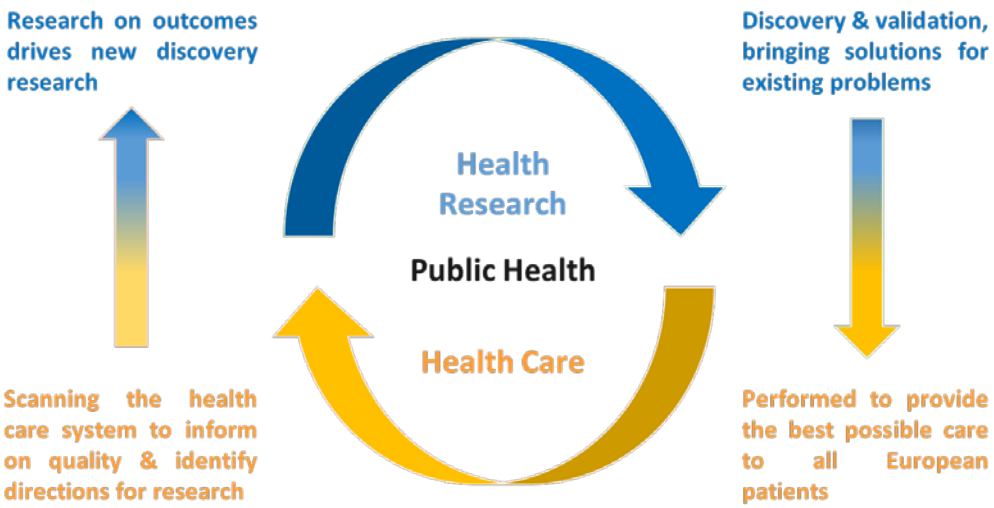
2. Health and health research form a unique and interdependent ecosystem

2.1. Health research and health care are intertwined.

Health is the **largest and most important economic sector,** with unique interdependence between research, innovation and patient care. It includes a range of activities from individual medicine, clinical care to global and public health. Investments in health have a huge impact: healthy people implies a healthy workforce. Several studies have estimated the economic return on investment through different approaches in specific areas such as cardiovascular diseases [14], cancer [15], brain diseases [16], and musculoskeletal diseases [17].

Health care is not only the consequence of research but is also **the setting for research**, in a close relation to, and iterating between, health care and health research (Figure 2).

Figure 2. The discovery and implementation process: iterations between health research and health care



Health research is about **working with human beings and studying the 'human model'**. Clinical research is performed in the health care environment. This brings with it unique properties, requirements and opportunities.

The **use of health data creates a wealth of opportunities that are amplified by innovations in the digital space**, enabling management and analysis of big data sets, and sharing of information. These opportunities are supported and broadened by breakthroughs in cutting edge technologies, such as 'omics', synthetic biology, and bioinformatics, which in combination with broad access to both longitudinal individual data and aggregated epidemiological and public health data, provide an opportunity to make Europe an eminent place for translational health research. Digitalization forms the basis of European health(care) networks and was in 2018 proposed by the High-Level Strategy Groups as a Key Enabling Technology, catalyzing new industries that will enhance the future health, security and wealth of all European citizens [10].

These opportunities are also highlighted in the RAND study [18], that stipulates the social and economic benefits that health data can provide to the health system. These include:

1. Empowering patients to more actively engage with healthcare decision making in healthcare, and in public health
2. Supporting health professionals and policymakers in clinical and policy decision-making
3. Enabling researchers and academics to enhance research quality and to undertake new types of analysis, research and innovation
4. Helping industry to more efficient and effective therapy development and validation processes, providing the basis for more personalized decision taking

Strong information systems are needed for implementation and guidance of health policies, the focus of the European Health Information Initiative of the World Health Organization, WHO,[94]. The WHO also put digitalization on its 2018 World Health Assembly agenda. Full deployment of digital innovation in health is still restricted to regions with strong e-health infrastructure and adapted policies e.g. Estonia. This therefore remains an area with strong, and as yet unfulfilled potential [18]. Breakthroughs in cutting edge technologies such as genome editing, cell engineering and synthetic biology in combination with data management, analysis and sharing will enable Europe to be the world leader in disease prevention and treatment. This requires cross-disciplinary practice – the combination and convergence of state of the art life science advances and digital health technologies. As noted [10], "Data management, analysis and sharing are absolutely crucial for the future of European healthcare. There is the opportunity to develop new electronic healthcare structures and share data such as cancer genomics, epidemiological studies, data from large-scale drug discovery and testing programmes and also the results of public health initiatives. This data sharing and analysis will inform the way we understand and develop treatments for disease. Secure networks and high-quality digital infrastructure and connectivity will be essential to ensure standardised and interoperable electronic patient and personal health records (strong control by the citizen/patient). Such networks, for instance in the form of a European bio-informatic system for cancer treatment, will allow remote consultations, participative and preventive healthcare solutions, and an equality of access to the highest quality of healthcare. Such advanced and integrated healthcare networks will enhance efficacy and contribute to lower public healthcare costs. This combination of emerging technologies provides enormous opportunities for the emergence of new industries in Europe not just based on life sciences but also coupled to other developments in informatics (big data, AI, software)" [10].

The current **divide in competences in health research (EU level) and health care (MS level)** is artificial and originates from the initial economic focus of the EU. Since 2007, EC structural funds have been increased and have focused towards the EU's new Member States to address inequities across MS, including in health care and health research [19,20]. Although improvements have been achieved in the health care sector, considerable challenges remain due to austerity measures and their impact on public spending, poor efficiency in the use of the funds, and a lack of strategic management [19,20]. Overall coordination of EU global and public health research and policy can contribute to reducing these inequalities and form a basis to ensure equity beyond the EU.

Health care is a national competence but cannot be separated from research. Health research at the EU-level can identify and address mechanisms that reduce health inequality

Meeting health research needs requires **input from many disciplines** including the social and environmental sciences, humanities and engineering, all of which are essential for the implementation of health research. This need for interdisciplinary action extends to health **policy:** Health in All Policies (HiAP)

is a policy strategy promoting an integrated policy response across relevant policy areas with the ultimate goal of supporting health equity [21]. In practice, this implies a strong programmatic and financial coordination of very different actors. Within the EC this implies different DGs (SANTE, RTD, CNECT, ECHO, ENTR, DEVCO, etc) and will also include partial participation of the social fund and structural fund in health research.

The importance of health **research for informing health care and health policies** is at the basis of the World Health Assembly resolution WHA66.22 calling for strengthening of health research.

2.2. Health research is performed in a complex regulatory framework

Regulations are necessary, but are complex and pertain to many aspects of health research [22-24]. Because of the complexity they can also present bottlenecks throughout the pipeline of health R&D, limiting patient access to innovative medicines, devices and therapies [25]. As the sphere of health captures such a wide range of conditions and challenges, regulatory requirements within different branches also diverge, for example the organization of clinical trials for rare indications.

Pertinent **challenges for rare disease research** include the relatively small number of patients affected, high costs, and need for international multi-centre recruitment which involves facing divergent procedures and legal frameworks across national borders [22]. In addition, the return on investment is often not considered as sufficient by companies to justify an extension of the label, and only the private company can request such extension [22]. In an effort to address some of these regulatory obstacles, the European Medicines Agency (EMA) developed *adaptive pathways* for cases of high unmet medical need: *Adaptive pathways* facilitates the authorisation of a medicine in a small patient population on the basis of less comprehensive data than is normally required, but to mitigate risk has an additional requirement that additional evidence should be gathered over time to progressively adapt licensing of the medicine [26]. These rapid approvals oblige to have more evidence on efficacy and risks over the time, which could be implemented by partnerships, including PPP, at European level.

Navigating the complexity of regulations in health research requires coordination to meet the needs of society and to facilitate health research to the benefit of the patients.

Individual-level health data needs to be handled with care. Data sharing and open science boost research and innovation, but generate ethical issues that need particular consideration within the field of health [27,28].

Health research needs complex regulation, to benefit patients, to facilitate, not hinder, research. The balance in this regulatory framework requires coordination and adapted approaches.

2.3. There is a need for unique, individualized approaches

Technological and scientific advance allow for increasingly **personalized and precision medicine**. Personalized or precision medicine (PM), integrates in depth and comprehensive data on an individual's geno- and phenotype, as well as lifestyle and environmental factors relevant for a specific person to

identify the most appropriate health interventions. PM is one of the most innovative areas in health research, at the heart of societal debate in the EU and represents a major opportunity for health research and health care [29,30]. Making use of digital 'big data' approaches allows to integrate massive individual-level data in population level studies. This approach offers many new applications, but requires also innovative ways for analysis of clinical data and clinical trials [31].

The EU Council conclusions in 2015 acknowledged the opportunities offered by PM for the treatment of patients in the EU, and the EC has been a driver for the development of PM approaches, devoting sustained and significant investment starting in 2010. In total, a €3.2 billion has been invested in PM research in 2007-16 across the medical innovation cycle 'from bench to bedside' by FP7, Horizon 2020 and the IMI [32]. The EU funded project PerMed has been launched to develop a joint European research and innovation policy for PM, and an International Consortium for PM (ICPerMed) involved over 30 European and international partners to define an action plan in 2017. This plan provides recommendations for the implementation of personalised medicine in transnational research and health systems [32-34].

The potential of precision medicine raises expectations for further improvement of disease outcomes and increased quality of care but requires further evidence and research into effectiveness and impact on overall health care

Despite very high public expectations, the full potential of PM has not yet been realized and only a limited number of PM approaches have so far translated into clinical application, except in the fields of cancer and rare diseases. This is due to the fragmentation of research efforts [35] and a paucity of suitable validated biomarkers that enable stratification into endotypes along causal pathways [36]. Implementation in clinical practice is also a major challenge because the translation of these mechanisms in therapy has proved difficult and less efficient than expected [35,36].

PM requires a multi-disciplinary approach, in the discovery of mechanisms through systems biology, in the development of novel diagnostics and therapies, and in management of care [37]. PM needs research on effectiveness and cost-balancing, given that the health care system in Europe is at risk for explosion of costs. PM therefore must be developed together with the health care sector, with at the center better treatment and quality of life for patients, and societal value.

2.4. Health is a societal responsibility and needs public investment

In Europe, **health care is one of the pillars of the social structure**, and a public and societal responsibility: Patients are not viewed as clients of corporations. The support to health research through public funding is part of this societal commitment. Support for health research is also part of a vision on science and knowledge as foundations of society [38-40].

The role of industry and SMEs in the chain from discovery to implementation is essential in bringing new products to the market. However, the role of public funding and coordination is much broader and supports the discovery research and first stages of entry into the pipeline as well as in the later, implementation phase and follow-up. **Public engagement for health research is driven by the societal value**. Some important research questions for patients and society are of little interest to industry. This includes for example, non-profitable areas such as lifestyle or education, comparing out-of-patent or widely used treatments, research that repositions a drug or technology in a different indication, and research on rare indications for which the return on investment would be insufficient. As well, the emergence of effective but expensive drugs in cancer calls for studies on optimal use of available therapies to counter huge threats for the budgets of health care providers as well as to ensure equal access throughout EU. The process of translating biomedical discoveries into drug development or new clinical applications has become increasingly costly, complex, long and risky, and **pharmaceutical companies have adapted their R&D models and investment in research** [41,42] In addition, private enterprise can change agendas in R&D in areas that are essential health challenges such as neurodegenerative diseases, and R&D activities are moving out of Europe. Pipelines for drug development change considerably over time not necessarily reflecting burden of disease.

Many successful drugs and devices have followed development of prototypes by publicly funded research, reducing the first-level R&D investment and risk for industry, yielding substantial benefits. Knowledge generated by public investments in science is often freely accessible to multiple other parties [43]. For instance, the development of a remarkably effective treatment for chronic myelogenous leukaemia resulted from decades of **publicly-funded research before patenting** [44]. Publicly funded research may also have applications in other areas, and with long delay many years or even decades later. A recent US report showed that NIH funding substantially contributed, directly or indirectly, to private-sector patenting [43,44].

It is therefore essential that public funding addresses challenges and needs of high public interest, and areas in which the industry is reluctant to invest if the product does not have an attractive market. Health research therefore **needs continued public investment**. Several charities are contributing substantially to the funding of health research and are part of this fabric of societal engagement.

The High Level Group on maximising the impact of EU Research and Innovation Programmes recommended in its report in July 2017 that citizens should be more involved in determining EU research and innovation priorities [1,8]. **Health research has a unique ability to involve citizens** through patient groups and society at large, to support this policy and the necessary public spending.

2.5. Health has no borders

Europe faces important **public health threats that cross borders**. Examples include the global spread of antimicrobial resistance, and emerging infectious diseases epidemics such as the recent Ebola outbreak that highlighted the need for a coordinated global response [45]. Pandemic preparedness has been one of the urgent medical topics at the G7/G20 Summits of the Heads of State in 2017.

Therefore, coordination of EU health research and policy need to extend beyond EU borders and adopt a global perspective. In its 2010 Communication on Global Health [46], the Commission emphasizes that "*public health policies ... require strong global institutions and coordinated efforts. … The EU should coordinate more effectively research on global health in order to address the highly fragmented landscape and identify shared global priorities for health research*." Even though some specific aspects of global health have been addressed in the H2020 calls, progress on the overall coordination has been limited to specific diseases, with the EU still lacking a comprehensive science-based structure or forum coordinating EU and member states' global health efforts which are effective and visible to the world and countries in need.

There is also a need to address questions at the **intersections of human, animal, and environmental health** as described in the "One Health" and "Planetary Health" initiatives [47]. New research frameworks should provide a better understanding of the ecological and environmental factors that impact on human disease to improve preparedness for zoonotic disease outbreaks, emerging infectious diseases in both plants and animals, and antimicrobial resistance [48].

Health research therefore needs a global and coordinated vision that is open to the world and takes a holistic 'One Health' approach – that is to improve health and well-being through the prevention of risks and the mitigation of effects of crises that originate at the interface between humans, animals and their various environments.

2.6. Prioritizing health research is timely

2.6.1. Health is a human right and a leading concern of citizens.

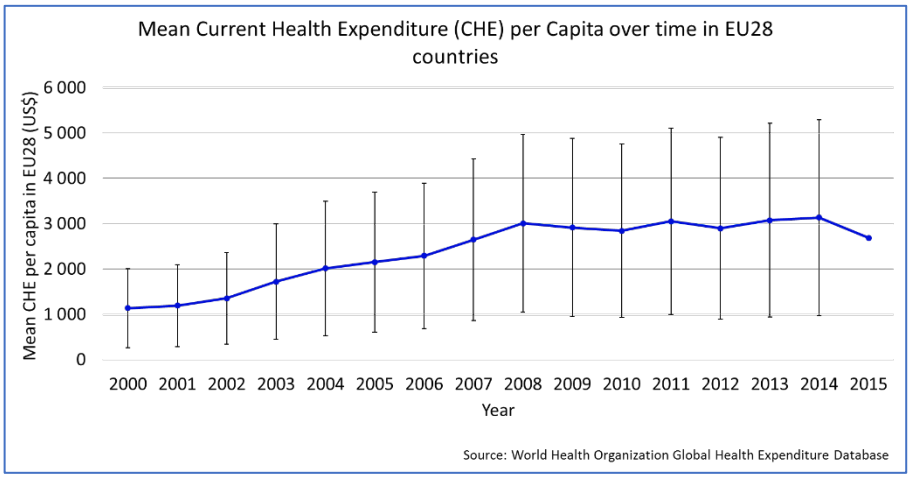
Across the world, **citizens are united in citing health as a primary concern [49-51]**. Health is an essential part of Europe's social model. It contributes to inclusive growth, social cohesion, and to the nurturing of a health economic environment conducive to investment [52,53]. Europe views health as a fundamental human right, including access to health care, liberty and equality in health. Protection of a high level of human health is entrenched in the Treaties of the EU. Citizens' health is a core priority for the EU [54] and in **the 2017 Eurobarometer, 70% of EU citizens demanded for more EU action in the field of health and social security [55].**

Good health underpins almost everything that people want – to be free of illness, to escape poverty and hunger, to work to secure independence, to gain fulfilment through education and learning, to be treated fairly and without discrimination, and to live in a safe environment [56]. Therefore, the United Nations made

health an integral part of the Sustainable Development Goals (SDG). Goal 3 calls to ensure health and well-being for all, at every stage of life[56]. Besides addressing all major health priorities, it also calls for more research and development, increased health financing, and strengthened capacity of all countries in health risk reduction and management[49,50].

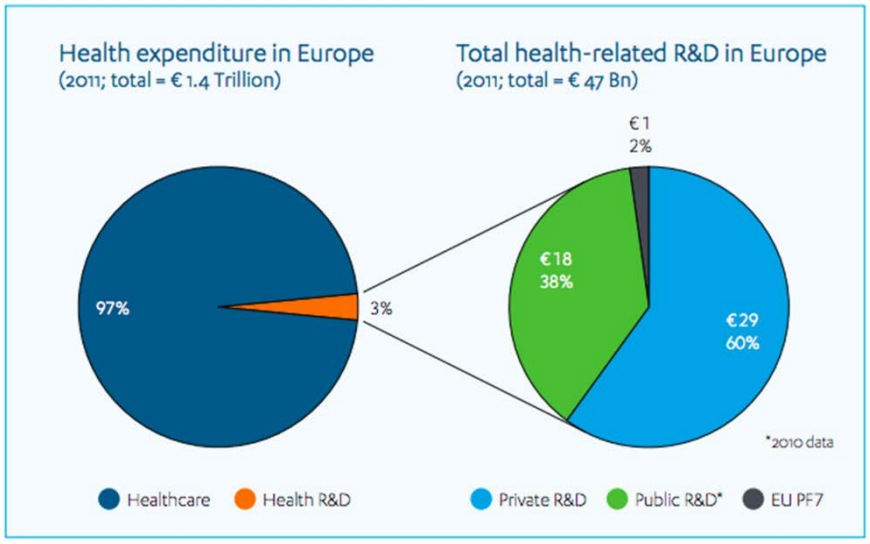
Investment in research is small compared to the cost of health care. In Europe, direct health expenditure reached 9% of GDP in 2015 (on average, up from 7% in 2000 [57]). The figure illustrates the rising health expenditure as average for capita and the rpid rise over time. The standard deviation further emphasizes the large discrepancies in spending across the EU.

Figure 3. Health expenditure per capita across EU28 – average and standard deviation.



The spending on health care as fraction of GDP vastly exceeds investment in research, which stagnated at 2% of GDP in 2015, across all disciplines and including all investors [58].
Spending on biomedical and health research in Europe is only a small fraction of the health-care costs (2-4% of health care expenditure [3,59]).

Figure 4. Relation between health care costs and research investments. Figure from[59].



The US spends substantially more on public funding in health research areas than the EU, up to three-times more per person per year [3].

Health is EU citizens' primary concern, health research is the basis of health and could unite Europe

Biomedical and health research are the drivers for better health and patient care through innovation and the implementation of novel findings into practice. Therefore, **health research should be positioned high on the political agenda**. Whereas health care is a MS competence, health research at EU level can help addressing mechanisms that will reduce health inequalities, support public health and transnational issues. As an example, the European Parliament debate "Can real world data advance equity of health care" discussed how patient-driven Real-World-Evidence (RWE) data (data being collected in settings outside of clinical trials) from 13 national Multiple Sclerosis (MS) registries could be pooled and analysed on the European level. This type of data, as was collected in the EUReMS project, could become the co-driver for regulatory decisions, for example supporting decisions on the pricing and reimbursement of medicines [60].

As a citizens' primary concern, health is a theme that can unite Europe.

2.6.2. A window of opportunities for health research in Europe

Opportunities for innovation emerge from strong discovery research, in life sciences, medicine, technology and humanites, in research institutes, and universities. ERC is stimulating the best and the brightest to develop novel ideas. The presence of a healthy SME system and unique models for peer-to-peer (P2P) collaboration that have been developed in Europe, promote translation. The education system in Europe is of high quality, although there are concerns for a properly trained workforce for health research, as discussed in 2016 [61]. The transfer from university discovery research to patent, university spin-outs and attracting venture capital is realized only in a small number of centers in Europe, and could also be improved. From the EU there are new initiatives to stimulate innovation through the EIC.

The EU constellation of a highly educated workforce, healthy ecosystem for digital innovation in health, societal engagement and a unique health care system conspire for leading research and innovation in health.

Global players Amazon and Google offer platforms for digital data, including in health, that have little competition in reach. However, Europe has the potential to take the lead in e-health and medtech **digital innovation** through access to comprehensive and high-quality health data. Cross-border solutions, investment in infrastructure, and an emphasis on reducing inequalities have the potential to create societal value through better health, as well as economic value through better health care. There is also an urgent need to establish a health data bank which provides public open access, is not driven by commercial and political interests and which adheres to stringent scientific quality control standards. The need for open access data was recently highlighted by the Ebola outbreak in West Africa. Making data available from multiple sources greatly facilitates the response to situations such as disease outbreaks through the availability of better, and more up to date information. New types of digital data, for example from mobile networks offer unprecendented potential (for monitoring population movements for example), but this type of data also

raises unprecedented ethical challenges that also need to be addressed [62-65]. Europe supports open science [66] and is working on developing an open science cloud. Europe has a duty as one of the few regions in the world with the technological and scientific potential to offer an accessible publically supported data for the use of Big Data in health.

In 2017, the **EC introduced digitalization of health and health care as a priority**. Technological advancement brings with it new opportunities, for example data sharing and open science. The world is rapidly developing better ways of collecting, storing and analysing very large data sets collected prospectively. New methods are being proposed for including historically collected and saved data in many different formats as big data methodologies become better understood. These processes are arriving very fast and they hold much promise for boosting research and innovation. They also present new challenges. Further innovation is needed for proper curation, storage and analysis of big data across nations, and mechanisms to ensure data protection and privacy are essential. It is important that policy and legislation is aligned with new technologies as they arise to prevent bottlenecks slowing the utilization of new technologies, as this would be a missed opportunity for Europe. Guidelines that enhance the re-usability of data have been put together in the 'FAIR' (Findable, Accessible, Interoperable, and Reusable) guiding principles for scientific data management and stewardship [67].

Europe needs a health research oriented body to manage these changes and exploit them to provide better health for the European population. Europe cannot fall behind in this area, which includes issues in the scientific, engineering, mathematical, health, medical, social and ethical domains – the full range of translational disciplines. In this area, novel policies and political decisions will be needed at a supra-national level, as well as a nimble strategic overview of these changes to facilitate European leadership in this health research and care field. Some concrete examples follow:

- Making medical and health data accessible across boundaries for European researchers (note that the recent GDPR facilitates such research; the rules for making medical data accessible across the continent needs to be considered, as it is likely to replace any need to physically move them).
- Promoting public health and epidemiological research on a European basis. This activity depends on analysis of very large amounts of aggregated data. This research is needed to prevent, to confine and to treat unexpected medical disasters and unforeseen pandemics.
- Facilitating interaction with similar initiatives globally. China, the USA, Japan, Australia have major efforts in modern medical informatics. These are state aided and also funded by private initiatives, notably from the major new informatics-based industrial conglomerates.
- Taking advantage of intellectual advances and innovation funded by and produced in Europe. Note that the European OpenScience Cloud and the Medical Informatics Platform of the Human Brain Project are examples of major EU funded projects that exist already.

Societal engagement in Europe is strong and patients are powerful partners in research policy, design and implementation, creating additional opportunities for health research and implementation. Patients are increasingly becoming key stakeholders in the research and development process. Under the funding of the H2020 Innovative Medicines Initiative (IMI) [68-70], a patient-led initiative, the European Patients' Academy on Therapeutic Innovation (EUPATI) [71], launched in 2012, aims to empower patients to engage more effectively in the development and approval of new treatments and become full partners in pharmaceutical R&D. One objective of EUPATI is to educate patients to enable them to make a meaningful contribution to the research process. The EUPATI project has published a set of guidance documents and

educational toolboxes on medicines research and development to facilitate patient involvement in R&D. EUPATI has already trained 96 patient experts on medicines development, clinical trials, medicines regulations, and health technology assessment.

2.6.3. Pressing and emergent novel challenges for health and health research

Current challenges for health which have been outlined previously [4], remain on the agenda. **Chronic and non-communicable diseases** lead the statistics for mortality, co-morbidities and reduced quality of life in an aging population. A **long-term commitment** is needed, as progress can be slow and industry support fickle, depending on market and profit considerations. Incentivizing research through prizes can have a short-term effect. Targeting major disease areas in a mission-oriented approach may stimulate joint efforts towards concrete goals, as outlined for cancer [72].

Global and public health challenges include infectious diseases and migration, both of which call for intensified cross-border research. Emergent diseases can be unpredictable, and require flexibility and preparedness. Moreover, ongoing global health inequity calls for coordinated European action in health research and (internal and external) policy, upholding and promoting European values.

In the present rapid **evolution in societal structure**, many changes have an impact on health, such as (loss of) employment and novel concepts for work in an increasing technological and urbanized society, the influence of social media and changes in attitude towards health and health care, and the education system that may be too slow in responding to the new demands. A comprehensive, multidisciplinary approach to identify directions and priorities in health research is necessary.

In a rapidly changing society we must respond to the major challenges in health with novel models for health research and implementation into health care

Despite a vast gain in knowledge on health and disease, there is still a large **gap in research implementation and evaluation of its outcomes**. In the clinical, health care setting, research on outcomes, effectiveness, and addressing wasteful treatments call for high-quality, investigator-driven clinical research, novel clinical trial models, as set out for the cancer field [24] and a European digital health platform, which integrates clinical and integral outcome data, as well as 'real-world evidence'.

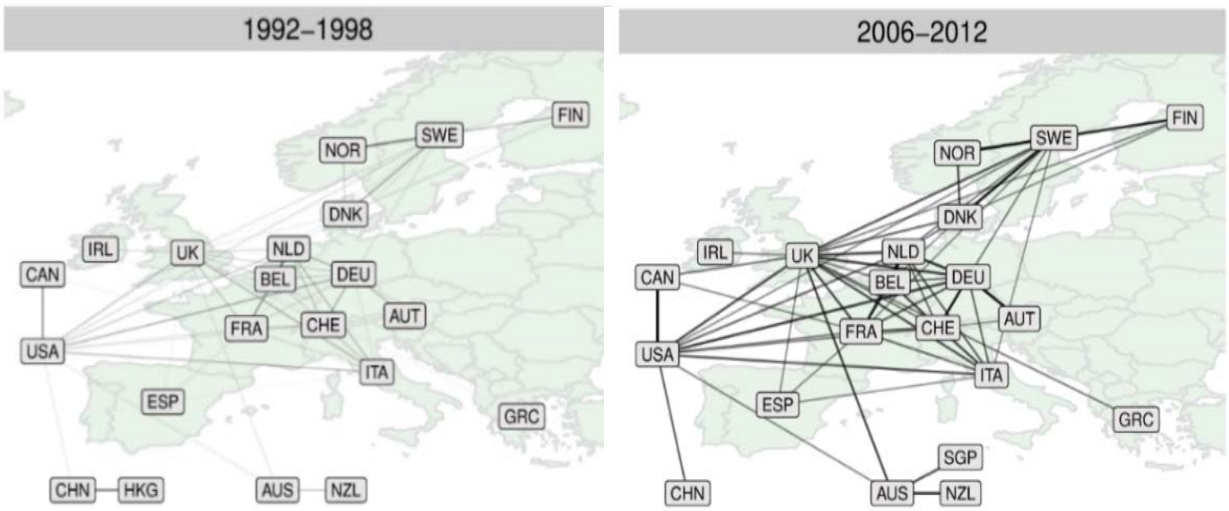
Adoption and implementation of health measures and health care guidelines require new models for evaluation of outcomes and societal engagement.

3. Europe must build on its achievements and address the needs for health research

3.1. EU programs lead impactful cross-border international research

Collaborative research leads to high impact output, and the **European Union (EU)** has been a global l**eader in facilitating collaborative research** through its framework programs (FP) supporting excellence and boosting innovation. In an analysis of the evolution in the worldwide output in cardiovascular medicine [73], joint publications within the EU, as well as, with other countries increased substantially, as illustrated in Figure 3.

Figure 3. Joint publications in cardiovascular medicine increased over time in Europe (from [73])

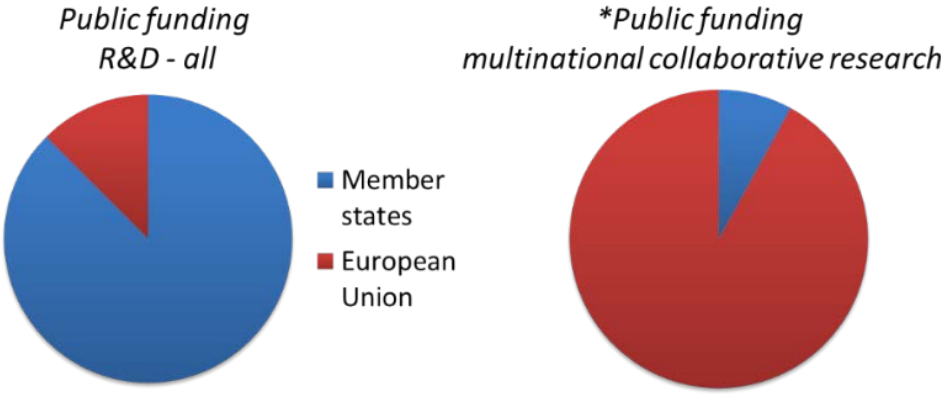


Countries with a high level of international collaboration scored higher impact and the collective EU27 output surpassed that of the USA.

In this study, Europe leads with respect to output and citations which may be related to the powerful models of cross-border and international research cooperation [1]. In addition to publications output, patents produced through Horizon2020 are of high quality and commercial value. Nevertheless, in the medical and health research, investment in Europe compares unfavorably to the US with consequently lesser output [3].

The major share of public funding to support research, is within member states. However, when it comes to investment and support for multinational **collaborative research across borders** the EU is the primary source of public funding.

Figure 4. The EU is the primary source of funding for collaborative research across borders



*Scientific Panel for Health, based on MS funding schemes and EC reporting

European research funding has evolved from a handful of programmes, to become an important component of the research and innovation landscape in Europe as further detailed in Appendix 2.

In the area of health, this has fostered major advances in knowledge and stimulated innovation (Appendix 3). The case of the **actions in infectious disease and orphan diseases** is a strong example. The EU programs addressing antibiotic multidrug resistance (AMR) brought on board member states and all stakeholders [48,74]; the global outreach by the EU were key to the advances made in this major health threat. One program collected data on the differences in AMR between countries. This data provided a call to arms for many policymakers in member states and national plans were rolled out for the first time to address the crisis. Other programs tackled behavioural change, for example a campaign in Belgium and France over antibiotic misuse (2000-2002) which led to changes in clinician- and patient attitudes and behaviour. Other projects tackled scientific, regulatory, and business challenges that hampered the development of new antibiotics [75]. Another EU grant supported the investigation of antibiotic use in food-producing animals in Europe. Awareness that the Netherlands was one of the highest European users of antibiotics in farming led to action: mandatory targets were set and met for reduced antibiotic use in animal husbandry. As food and associated resistant bacteria cross national borders, this increase in meat safety has benefitted Dutch consumers as well as consumers throughout Europe.

The International Rare Diseases Research Consortium, IRDiRC [76,77], EC and NIH joining forces successfully facilitated R&I in rare diseases. The focused and mission-driven approach in this program has led to the identificaton of >200 novel therapeutics of which many have alredy become available on the market [78]. Another action in rare diseases is the recent creation of the European Reference Networks (ERNs), virtual networks involving healthcare providers across Europe [79].

The EU started powerful models of stakeholder collaboration. The **IMI programs** are the world's largest public-private partnership (PPP) in the life sciences [68-70]. They address topics directly relevant to advance implementation of diagnostics and treatment. In IMI2 the sharing of data and resources may set an example for PPPs with wide impact.

EU support has **fueled long-term alliance**s. The cancer community united through EU programs such as the EurocanPlatform, and built up towards a comprehensive, inclusive and high level consortium started in 2014 to create a virtual 'e-hospital' enabling joint research programmes and development of innovative new generation clinical trials in the Cancer Core Europe [80]. Imaging has developed as a powerful tool for prediction, diagnostics, treatment monitoring and developing targeted therapies. Boosted by a number of EU projects, the European Society for Molecular Imaging emerged [72]. The European Strategy Forum on Research Infrastructures, ESFRI, has led to the creation of the BBMRI-ERIC biobank as an intergovernmental structure [81].

3.2. A rich landscape of EU funding but with several limitations.

In the evolution of the EU framework program design (Appendix 2), newly added instruments have enriched funding opportunities and some actions have provided visibility to health research such as the FET flagship in brain research [82] and EIT Health [83]. All together, a set of dedicated instruments and calls for biomedical and health research provide opportunities for discovery research, for innovation and partnerships, as illustrated in Figure 5. The drivers and aims for each of these instruments vary and the downside of this rich landscape is the **increasing complexity.** Furthermore, despite the array of

instruments, the main public investment in research still is in the national competence through national research programs and funding, as reported for cardiovascular diseases [84] or at aggregate level in the commissioned report by Deloitte [59], that furthermore highlighted the investment by industry.

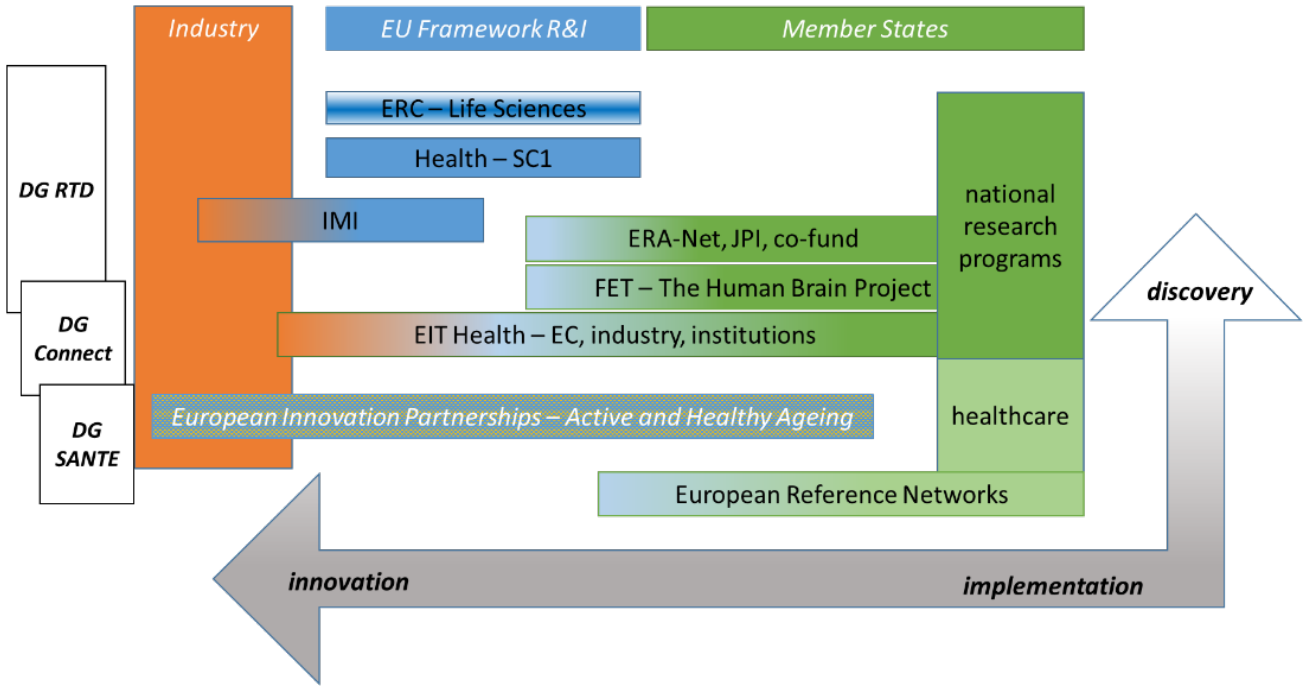


Figure 5. Landscape of instruments for biomedical and health research administered by EC, alone or in partnership with industry and member states. As per Figure 1, the majority of public funding is through member states.

Despite this apparent wide offering, it is not sufficient – not in its scope, not in addressing health needs.

Excellent EU programs have pushed health research forward but are not sufficient - a new model is needed to address the challenges for health

- Calls for collaborative research in SC1 Health are vastly oversubscribed, even more so than in the overall H2020 program. As a result a substantial number of **high-quality research projects are not funded.** That oversubscription exists also provides evidence of the large potential for high quality health research in Europe.
- The **lack of sustainability** for collaborative projects leads to waste. EU projects often generate networks that maintain fruitful scientific interactions. However, the lack of continuation of funding undermines sustainability of the collaborative research and threatens data collections such as cohorts, biobanks and registries.
- **Future novel, emerging challenges** will need increased health research support, such as in public health and migration, implementation of a European digital health platform, and fighting major diseases in a mission-oriented approach.
- Access to health care in Europe is not equal throughout member states; participation in **health research is not equitable**. A more inclusive participation in health research would facilitate subsequent implementation of better health care.

- Major potential to advance health exists through building research programs on initiatives such as the European Reference Networks and linking R&I to health care. Such advance is severely hampered by the **lack of a strong cross-sectoral and cross-border collaboration**.

3.3. Insufficient visibility hampers global leadership

The potential for Europe in taking leadership is shown among others in the worldwide International Rare Diseases Research Consortium (IRDIRC). Individual programs of high prestige, such as the visionary, science-driven, large-scale research initiatives addressing grand scientific and technological challenges (EU FET flagships), the Human Brain Project, or the EU commitment in fighting emerging epidemics have visibility, but the overall investment in health research through the different DGs, RTD as well as SANTE, CONNECT and GROW, and through the P2Ps, is much larger and with high impact. Nevertheless, the **visibility is associated with programs, not the EU as a whole.** Member states, the largest investors, do not have a common policy. Some national programs have strong visibility such as the Sanger Institute in the UK, cancer research centers in Germany, the German centers for Health Research (DZG), and others. In the cancer field a collaborative effort of multiple member states is growing but overall the field of health research remains fragmented.

In comparison, the US National Institute of Health (**NIH**), the largest public funder of biomedical research globally, presents a comprehensive, highly visible, program to enhance health and reduce illness and disability. NIH promotes treatment and prevention, expands the biomedical knowledge base by funding cutting-edge research and cultivating the biomedical workforce. Evidence of the varied, long-term impacts of NIH activities is strongly publicized, ranging from specific studies to broader analyses of NIH as a whole [85,86].

Canada has only recently brought together a number of more fragmented programs under the Canadian Institutes of Health Research (**CIHR**) [87]. Created in 2000, its mission is to create new scientific knowledge and to enable its translation into improved health, more effective health services and products, and a strengthened health care system. CIHR has different instruments, funding of both investigator-initiated research, as well as research on targeted priority areas; building research capacity in under-developed areas and training the next generation of health researchers. It aims for impact through new policies, practices, procedures, products and services. Evidence of the impact of CIHR activities comes through the Health Research in Action stories, and broader analyses. CIHR is part of the Health Portfolio which supports the Minister of Health in maintaining and improving the health of Canadians [88].

The lack of visibility of the wide-ranging investment and success of programs in health research in the EU contributes to the lack of societal recognition and hampers engagement in global interactions. Synergy, coordination, evaluation and dissemination of the impact and value of health research and leadership under a European Council for Health Research can address these weaknesses. The **European organization cannot copy NIH or the CIHR, but must find its unique strengths from the EU and member states participation**.

European health research needs visibile leadership in a joint action of EU and member states

Indeed, several **European countries have taken initiatives** to address the challenges for health research on a national level with strategic programs, that could propel joint actions.

- Countries have implemented research activities under the Ministry of Health, to address issues of effectiveness of treatments, or identify priorities, as exemplified by the National Institute of Health Research in the UK, and the Netherlands ZonMW agency. Portugal launched a joint initiative between Ministries of Health and of Science and Education.
- Programs have been designed reach out beyond the national borders, e.g. between the Scandinavian countries (NordForsk) or in Portugal in multilateral agreements.
- Policies are enunciating the need for a larger collaborative effort in Europe. For example, the Gago conferences on European Science Policy, initiated in February 2018, provide an international forum to strengthen the debate on emerging issues of research and innovation policy in Europe, and promote the necessary involvement of major stakeholders in policy making and the diffusion of knowledge in science education and culture. The Conferences seek also to strengthen international scientific and technological cooperation networking in Europe towards a positive impact on a global scale [89].
- Strategic actions support collaborative research, across the borders of basic, clinical and innovation research gets strategic support. Germany established six "German Centres for Health Research" (DZG), focused on various disease areas such as cancer, neurodegenerative diseases, infectious diseases etc. in order to improve the outcome of research and strengthen the translation into treatment and application. In each centre, university institutes and institutionally funded research institutes cooperate on jointly set out priorities in research and translation. The members and the centre itself are quality monitored on a regular basis and the whole concept just went through a positive review process. Each centre is specifically funded by the ministry. In France as well, six high level centers (Instituts Hospitalo-Universitaires) were created each of them focused on one domain (cardiology, genetics, neurology, cancer…). Other member state have developed strategic initiatives and funding schemes for collaborative research to advance particular areas, e.g. for cardiovascular disease in the Netherlands.

On a European level, large-scale, long-term comprehensive programs or strategies are still lacking. Existing national consortia could become more inclusive by associating other member states and would help to develop better coordinated national research strategies. The combination of national and European structures and funding schemes would greatly enhance collaboration, quality, synergies, efficiency, impact and visibility, and strengthen global competitiveness.

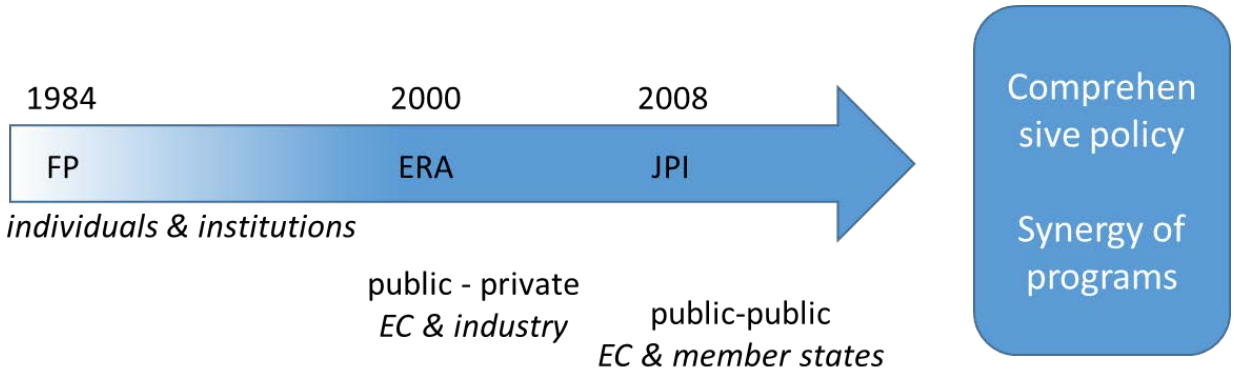
4. Health research requires cross-sectoral structures and a new model for collaboration

4.1. Towards synergy and a comprehensive policy for health research in Europe

Collaborative work in the framework programs originally consisted of **individual research groups** embarking on a joint project within calls set out by the EC, with each call involving the Advisory Groups and Program Committee. Many H2020 projects still follow this format but the funding landscape has grown (Appendix 2).

ERA-NET and Joint Programming Initiatives (JPIs) were the next step: **member states in P2P** initiatives commit to jointly funding programs laid out by the High Level Group on Joint Programming. Programs in major disease areas (neurodegeneration, antimicrobial resistance, cardiovascular diseases) have been very successful, but a shortcoming has been the weaker investment in health research towards clinical implementation and innovation. As noted, the influence of research in the JPI on member state policies has been limited and lack of a comprehensive strategy, and synergy with other instruments are major shortcomings [90].

When considering how to enhance the impact of health research, the time has now arrived to think beyond multilateral collaborations.



A comprehensive policy at a higher level should be developed by engaging all stakeholders as partners. The **EU-wide vision and strategic plan** for funding in health research should cut across health care, science and innovation, enhancing the alignment of EU and member state programs, identifying priority areas for synergistic actions, and bringing an added level of societal involvement. Implementation, as supported by targeted funding in novel partnerships that cross-borders and include multiple actors, would address current limitations of fragmentation and continuity. Addressing and engaging society will contribute to focusing on societal impact, with consequent economic benefit.

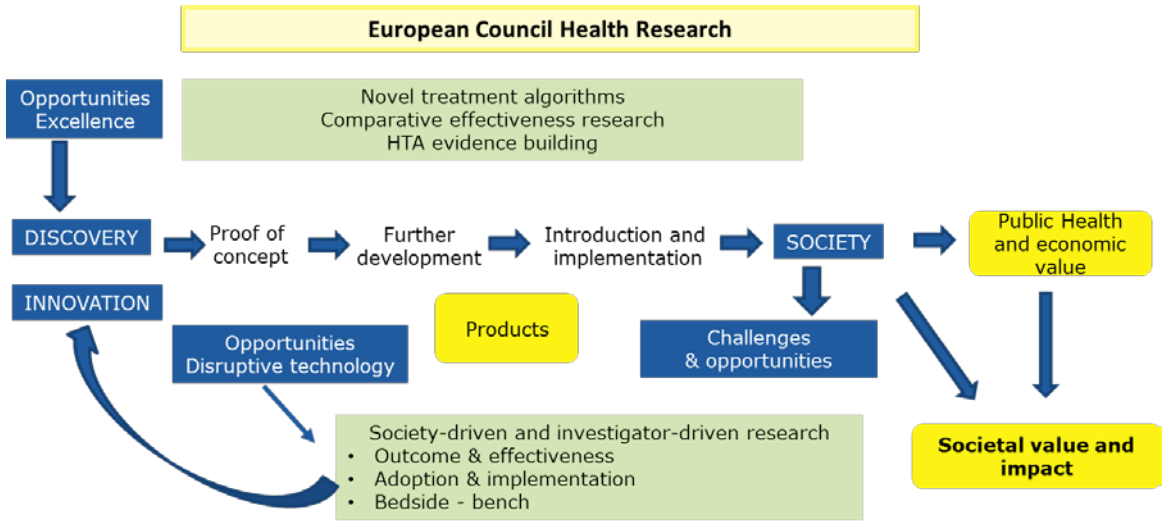
Moving to a next level of collaboration and synergy in Europe is an **opportunity for simplification** in the current array of instruments, focusing on efficiency and societal impact for health.

4.2. A European Council for Health Research is a concept to boost health through research

The SPH calls for establishing a European Council for Health Research as a body within the European Commission. The European Council for Health Research should bridge different DGs in accordance with its mission: *to increase the **impact** of health research to achieve better health and well-being of citizens, thereby creating **societal** and **economic value** for Europe and the world.*

As was established during the SPH's March 2018 Workshop on Impact, impact relates to 'an effect on, change or benefit to the economy, society, culture, public policy or services, health, the environment or quality of life, *beyond academia*'. In addition to the need for excellence, professionalism, and resources, delivering impact to patients also requires time. The European Council for Health Research focuses on participative, people-centered, excellent research that is on the path beyond discovery and towards implementation including translational science, i.e. turning knowledge into products. It will acknowledge the continuum and re-iterative process from bench to bedside and back that is inherent to health research, and include **evaluation of societal and economic impact**. This will close the circle of research, innovation and health care, enabling feedback about opportunities, new discoveries and innovation.

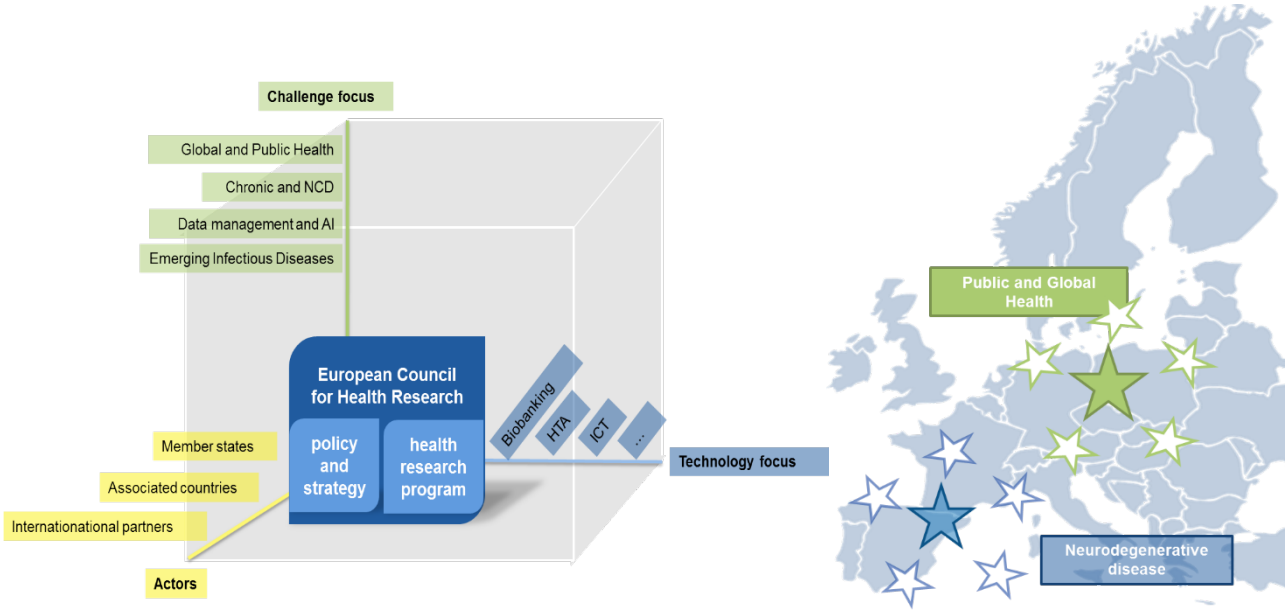
Figure 6. Focus on participative, people-centered, excellent research that is on the path beyond discovery and towards implementation



Research programs should focus on the mission to achieve societal impact and health gains with excellence as guiding principle. Assessment of societal impact will be ingrained in the EuCHR activities. As was established during the SPH's 2018 Workshop on Impact (Appendix 1), planning for impact increases the likelihood of achieving impact. Indicators for success need to be defined and followed through the course of projects and beyond. Sustainability is essential for health impact.

To maximise impact the optimal framework should allow for customization and regional differences, as exist in Europe. One potential design for an European Council for Health Research would be to orient it around major societal challenges through the creation of Health Research Consortia around specific topics (Figure 7). Many diseases require long-term commitments, yet programs should remain open to changing conditions and demands.

Figure 7. One potential design for an EuHCR: orientation around societal challenges



A core for this type of organization already exists in some countries as described above and could be expanded upon to build an organization that tackles priority areas (such as public health challenges, healthy aging and mental health) holistically, using a comprehensive range of approaches (e.g. digital innovation, health technology assessment) and cutting across research and health care. Consortia can build upon national structures, creating and exploiting synergies between national and EU funding. Additional funds from EuCHR can support the European coordination effort and stabilize structures of excellence. Joint cross-border efforts would enhance the opportunities to create larger data repositories for precision medicine and facilitate inclusive approaches, driving the mission to reduce inequalities across Europe.

Within its mandate the European Council for Health Research will:

- Create a long-term **vision & strategy** for health research, **science-led**, ensuring citizens' engagement at all levels.
- Engage **member states & EU** in joint actions to fund health research – across the **R&D and health care** sector – and build novel partnerships with the **private sector**
- Provide **visibility for European health research** and engage with **international partner organizations and funders**

Through its actions the European Council for Health Research will

- Provide the necessary **extended time-window** and breadth of collaboration needed for health research by supporting successful multinational networks and scientific communities in pursuing their strategies even after conclusion of EU funded projects
- Support the creation, maintenance and access to high quality, federated and accessible data sources, so that **digital opportunities** can be leveraged, and facilitate access to European research infrastructures.
- Support **translational** science to bring novel treatments to patients and bridge 'gaps' in the network of health research towards **implementation**, including measures enabling rapid approval when needed
- Use health research to address **public health challenges** and health **inequalities** in the EU and beyond
- Focus on **societal benefit** with a long-term economic impact

With this mandate the European Council for Health Research will complement the strong discovery programs within the ERC and the innovation-oriented research within the EIT Health and the intended European Innovation Council. This is an ambitious proposal. To overcome Europe's current health research challenges requires a cohesive holistic view, developed through the comprehensive involvement of diverse stakeholders, and strong balanced governance within the EuCHR.

4.3. Governance of a European Council for Health Research

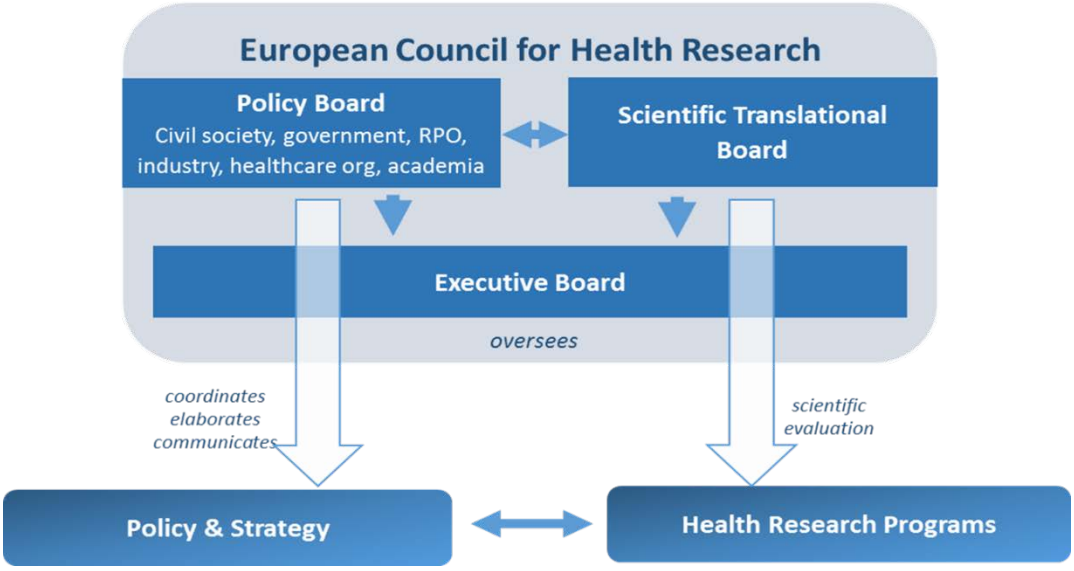
The European Council for Health Research will provide guidance, leadership and support for health research in Europe.

To organize the tasks, the governing bodies should include

- A **science-led board of all stakeholders** for **policy and strategy** development focused on **synergies,** alignment and facilitating health research towards implementation in concert with all stakeholders
- A **translational, implementation board** supervising health **research programs** and support for novel partnerships in health research with funding that is complementary and additive to the current budget

This dual mandate requires a balanced governance (Figure 8), between the policy sounding board, and the translational experts' board for the implementation. Care should be taken for strict separation of interests and powers, when implementing programs (cfr. ERA governance). The **Policy Board** is the platform for **policy** design and should be an inclusive stakeholders' forum. The **Translational Board** should draw experts from academia and implementation stakeholders and provide **scientific guidance for programs** within the strategy and priorities of the Policy Board. Several high-level organizations can identify individuals to take up positions in their expert capacity. Overall, the organization should be science-led, with an executive group that comes from both the policy board and the translational board.

Figure 8. Governance of the EuCHR



The European Council for Health Research should be based within the European Commission, providing a flexible and broad working environment, drawing on experience and leadership in EU-wide actions. The EuCHR should bridge different DGs in accordance with its mission but needs to be anchored.

Owners of ongoing funding programs and representatives of existing European initiatives could join the EuCHR Policy Board. The long-term aim is to simplify and defragment the European funding landscape under the umbrella of the European Council for Health Research, creating a one-stop-shop for European health research strategy, development and implementation and a clear entry point to European health research expertise, infrastructures and funding.

4.4. EuCHR Resources and Funding

By creating synergies between funding programs in a comprehensive approach, the proposed EuCHR creates opportunities to use the **available budget more effectively** and reduce waste. Hereby the EuCHR can act as an honest broker between different stakeholders, explore national funding programs and organize cross-border and cross-sectoral collaboration within similar focus areas for creating synergies and optimizing resources.

Nevertheless, stepping up beyond the current H2020 budget by reaching out to **additional funding sources** is necessary to ensure that health research funding expands to serve the strategic agenda. A re-allocation within the existing budget is neither sufficient nor desirable. Funds dedicated to discovery research, such as in the ERC, must be protected. Funding schemes must allow for inclusive program participation, beyond EU membership.

Funding could be leveraged through a variety of mechanisms:

- From within the **financial framework of the EU**. Use of additional funding has previously been realized for ambitious programs such as the IRDiRC, and for the AMR program. Dedicated use of European Structural and Investment Funds (ESIF) has been called for and applied in the health sector [91]. The EU should also provide the guidance and quality ensurance for the programs that are distributed among participants.
- **Partnership with national funding**. Important research activities for the EuCHR fall under the authority of health ministries. The involvement of national departments for health and science in negotiations is therefore essential.
- **Novel partnerships with the private sector.** IMI and other PPP are valuable examples, but novel avenue could be pursued, including payers and citizens[b]. Examples include pre-competitive PPP in health technology and data-driven health-care solutions as well as new collaboration frameworks like academia's participation in industrial development teams and technology networks, the creation of joint-value programs and resource-sharing, and development of new business models with enhanced societal responsibility.
- EuCHR will provide mechanisms to allow Europe to speak with one voice and create **synergies in funding with international funding** institutions more efficiently.

[b] For example, for big data, the “Big Data Value Public-Private Partnership”, for medical technologies the “ECSEL Joint Undertaking”.

4.5. EuCHR – added value for the EU

A European Council for Health Research enhances competitiveness, provides visibility and creates **added value**:

- *For the political leadership in Europe:* a next logical step in a growing program around health – providing scientific leadership and visibility to the program – facilitating intersectoral collaboration – mobilizing additional resources – responding to citizens' primary concern – speaking with one voice for Europe
- *For the health research community:* sustainability for very ambitious approaches and long-term projects, preventing loss of investment in time and resources
- *For funders:* optimizing resources – potential for intensified collaboration & mobility – an instrument for stronger global interactions
- *For society:* enhanced possibility for engagement and participation – benefit through better health and reduction of inequalities
- *For industry:* a platform for participative decision making – potential for novel partnerships & faster path to market

A comprehensive policy and strategy can take full advantage of inputs from each country to promote interdisciplinary team science (http://www.acmedsci.ac.uk/file-download/38721-56defebabba91.pdf/) and provide a sound mechanism for developing standard operating procedures for pan-European Research. It can enable combining the experience of different countries in helping others in building their research activity.

A European Council for Health Research can create a stronger connection to other large bodies dealing with research such as the NIH with increased opportunities to contribute to Global Health agenda.

Faster innovation, better, easier, avoiding waste of time and of money, heading the international competition.

4.6. Implementation and translation into practice

The proposal for a European Council for Health Research to increase the societal impact of health research and thereby improve health calls for political action.

Global leadership has already expressed the need for action in health and the proposal aligns with several resolutions and recommendations at the highest level. Good health and wellbeing is number three of the 2015 Sustainable Development Goals of the United Nations [56]. In the United States, a consensus study report of the National Academies set out a path for global health and the role of the US, emphasizing the importance of international collaborative efforts, of improving R&D processes and developing digital health [92]. The World Economic Forum 2016 has emphasized the value in health care [12] as has the High-Level Strategy Group on Industrial Technologies (2017) [10]. The report of the High Level Group on maximizing the impact of the EU R&I Programmes (2017) [1] stressed the importance of a mission-oriented, impact-focused approach to address global challenges, to align EU and national R&I investment and to mobilise and involve citizens.

A European Council for Health Research responds to these recommendations and can provide the necessary leadership for a mission-driven [93] research program.

The most important voice to consider comes from society. Health is the major concern of citizens. Therefore measures to improve health should be high on the agenda.

As stated at the 2017 World Health Summit, health is a political choice. The current dialogue on the future of the EU should include actions to bring health research in Europe to the next level, with inclusive, visible leadership and impactful programs. The road to implementation of a European Council for Health Research requires intense consultation and open exchanges of stakeholders and policymakers, spanning the domains of health and health care, science and innovation, and finances. Those discussions will reveal difficulties but may also identify additional opportunities.

Engaging in this dialogue is urgent and necessary.

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Appendix 1. Workshop 8-9 March 2018 'Impact of Health Research for Society' - executive summary

Research funders and program designers are constantly challenged to maintain an effective and efficient funding system in order to allocate resources, while justifying the investments in scientific research towards their stakeholders. Estimating the returns arising from health research demonstrates accountability for public and charitable research funding to taxpayers and donors.

In the field of health research, it is difficult to describe systematically the nature and extent of the returns to the investment of a whole body of health research, some of which may inevitably be less fruitful. By definition, research activities are risky and their returns can be unpredictable. Nevertheless, it is important to understand how underlying research is translated into benefit for patients and people, the economy and society as a whole, and look beyond financial value.

The workshop aimed to gain better insight in the nature of societal impact, as expected by different stakeholders, how to measure impact and whether impact can be enhanced through better design of research funding programs.

Impact has specific meaning and value for research funders, health care payers, patients and society.

In the UK, the research evaluation framework and related studies offer insight in different types of impact from biomedical and health research and ways of assessing impact. In the direct impact, a monetary gain can be calculated, as well as health gain, but there can be long time lag. Additional impact comes from spillovers in other sectors. Besides effectiveness, it is also important to consider efficiency of the funds invested.

As a major funder, the European Commission is bound to evaluate impact of its research programs. While this process is set out in the H2020 regulation, the Commission also is building new tools for better insight, taking into account the time lag in biomedical and health research and using mixed methods. The mid-term evaluation emphasized the need to enhance societal value of the research funding programs.

The rising costs of health care are a major challenge to the social system and are not necessarily translating in improved life expectancy and quality of life. A re-design of health care, patient-centred and with clear standards to measure outcomes may curb what could otherwise become an unsustainable system. Incorporating new knowledge requires methods to assess effectiveness and above all the political will to implement changes, involving all stakeholders in the process. The patient should be a co-producer, systems should be driven by knowledge, focused on value, and meet challenges with transformation.

When considering public health, health inequalities across different social groups are not sufficiently taken into account. Prevention and health promotion remain subsidiary to 'cure and care' but could have major impact on public health. Multidisciplinary approaches including education and behavioral sciences can enhance effectiveness of programs. Pro-active dissemination of this evidence to policy-makers will incentivize further investment for stronger societal impact.

Health gain is a major element of socio-economic impact and needs better tools. Registries and real-world data need cross-border agreed-upon standards for outcome measurements. Investigator-driven health research and implementation studies can enhance insight into effectiveness and need more support. Lastly, the workforce for implementation and assessment needs to be nurtured. Physician burnout is a threat and a there is a shortage of data science experts to extract real value from the vast amount of data that becomes available.

Assessing impact of biomedical research – an evolving field requiring broad inclusion of stakeholders and adapted methods

Evaluation of the impact of research programs uses key performance indicators but needs to move beyond the classic numerical output data, such as bibliometrics, that policymakers have come to rely on. When assessing broader societal impact, different indicators that are project-specific are necessary. The long timeline for translation and implementation of knowledge into products should be considered. As used in the UK exercise, narratives can be very powerful to capture impact across the long timeline and an effective means of communication to the broader public.

Canada has a strong track record in impact assessment and Alberta Innovates has developed a fine-grained model to assess impact of programs on 'health and wealth'. Important elements include the planning for impact within the program design, considering who will benefit and the long term, sustainability, with evaluations along every step of the program and beyond. This requires the use of multiple types of data, mixed methods and cross-sectoral approaches.

Patients' experiences underscore the value of broad stakeholders' involvement. Insights from registries depend on data quality and stimulated by an initiative of the European Medicines Agency patients were instrumental in the stakeholders' collaboration to improve data collection and quality.

When emphasizing the importance of impact, it is equally important to consider that success cannot be guaranteed and that open, investigator-driven bottom-up discovery science can be (the start of a chain of) impactful research. This needs to be treasured, and a level of trust, and sufficient risk-taking are essential to advance knowledge and subsequent impact. 'Negative' data are important and need proper channels for information sharing as they are not highly valued in the classic publication channels.

Assessment of impact requires expertise and experience, and further research to optimize methodology is essential. Equally important is the inclusion of researchers to effect a change in culture and the researchers' engagement to consider and to show the value of their research.

Designing health research for impact requires co-creation and communication

The Innovative Medicines Initiatives' program of the European Commission was set up to accelerate the innovation process in drug development, creating a public-private partnership to share risk and data between companies and the public sector. IMI programs have been focused on outcomes that are transformative for industry and with clear value for society. Evaluation of impact is an ongoing exercise and includes developing clear communication to all stakeholders.

Public funding of health research administered through the Dutch Organization for Health Research and Development (ZonMw) focuses on promoting implementation of knowledge into action. In its activities, ZonMw includes patients and stakeholders and applies methods for impact assessment at different levels for accountability, analysis and allocation of its programs. This approach ensures data that are apt for advocacy towards policymakers.

In the UK, the government has been responsive to impact evaluations and designed new policies that include the creation of an overarching body bringing together different research councils and bodies. Impact has become part of the program design and impact must be embedded in research proposals and reporting. The methods for assessment need however further refining to be 'minimally invasive' and as noted above, this requires dedicated expert research, as part of developing science on science policy.

The health programs within the European Commission are geared towards moving beyond evaluation of reaching program objectives and increasing impact. This requires translation of outcomes data in actionable plans for health care. Focusing on implementation of knowledge, the Commission can take a lead as a broker across borders, and work with member states. Sustainability is one of aims.

As a charitable foundation Wellcome, is engaging with the research community and with the public in program design and in evaluation of impact for society. Wellcome uses different indicators to measure success and considers policy changes as one of the higher levels of impact. A continuous and in depth public dialogue, including addressing controversial issues, is part of the process.

At INSERM, general principles guiding research policies for funding seek to balance programs with short- and long-term impact, and between society's priorities and objective needs. Creating political will to address barriers for implementation of research results needs the gathering of all stakeholders, including patients and payers. Anticipating and addressing ethical issues that may arise during implementation reduces later barriers.

Co-creation and broad stakeholders' engagement during project planning (funding stage), translation and through the innovation chain are means to enhance impact. The final steps of pricing, reimbursement and access to products must be part of the planning and payers should be involved at early stages. Comprehensive, long-term follow-up and cross-border collaboration will enhance impact.

Conclusions and recommendations

- Societal impact of health research includes but is not limited to economic return. Economic return can be calculated and is substantial. A long time-frame must be taken into account.
- Health gains, reducing inequalities and cost containment of health care are specific aims for impact of health research. Health research needs better tools for achieving these specific impacts, including cross-border standards and high quality data on outcomes.
- Implementation of research results to achieve these impacts requires transformative action with a culture change in the professional and research community, and inclusion of dedicated data scientists.
- Research projects should be designed in co-creation with all stakeholders, putting health promotion and patients' outcomes at the centre, planning for impact from the start and anticipating on potential barriers to implementation.
- Indicators for success need to be defined and followed through the course of projects and beyond. Sustainability is essential for health impact.
- Communication and public dialogue are essential to achieve societal impact and engage with policymakers.
- Evaluating and facilitating impact requires expertise. Increased investment and research on impact evaluation are necessary.

Appendix 2. A history of European research programs

European research funding has evolved from a handful of separate programmes, to become a major component of the research and innovation landscape in Europe[c]. The progression of the research landscape is described in this section.

1970s and early 1980s: No legal framework for research, first research programmes adopted on the basis of Article 235 of the EEC Treaty

Research activities were a key component of the Treaties establishing the European Coal and Steel Community in 1951 and the European Atomic Energy Community in 1957. However, EU research funding was limited to coal, steel and atomic energy, and there were no provisions related to research policy in the Treaty establishing the European Economic Community (EEC) in 1958.

It was not until 1972 that the European Commission (EC) proposed to define and implement a Community research policy.[d] This initiative was justified not only by the Community enlargement but also by the need for the Community to face increasing 'competition through innovation', especially from the United States and Japan. This initiative was also based on evidence that large research programmes addressing social needs were required. This common policy wbased on two dimensions: the coordination of national research policies and the cooperation of the Member States.

1984: First FP

In 1984, the first framework programme (FP) was created to rationalise research funding under a single framework.

1986: Single European Act and research policy in the treaty

The first FPs in the 1980s and 1990s (FP1 to FP5) were small and initially supported fundamental research. The Single European Act, signed in 1986, included for the first time a specific chapter on research, which put the emphasis on applied research aiming at supporting the competitiveness of European industry and enshrined research policy in the EEC Treaty. It defined coordination of national research policies, and provided a legal framework for the adoption of the Community FP for research.

Development of FPs

The main aim of the FP was to define the objectives, i.e. the topics and areas on which research cooperation will be funded at Community level. In the first three FP, the coordination of national and Community policies

[c] https://ec.europa.eu/programmes/horizon2020/en/news/horizon-magazine-eu-research-framework-programmes-1984-2014

[d] http://www.europarl.europa.eu/thinktank/en/document.html?reference=EPRS_BRI(2016)579098

remained at a preliminary stage[e]. A wider international dimension was progressively built into EU research policy. Transnational cooperation was progressively extended to more and more countries beyond the EU. In recent years, the Framework Programmes have also featured new forms of support in the field. They favoured the creation of large joint undertakings that bring public and private actors together, while Member States (MS) have gradually increased the level of research coordination.

2000: ERA

In 2000 the European Research Area (ERA) was launched which allowed public-public and public-private partnerships.

2002-2006: FP6

2002-2006 saw the launch of FP6 and in 2007 the Lisbon treaty came into action. It recognised research as a shared competence and provided the legal basis to implement ERA. The first ERA-NET scheme for public-public partnerships in member state collaborative programs was launched under FP6[e].

2007: Lisbon treaty & ERA

2007-2013: FP7

ERC, IMI, JPI

FP7 was conducted between 2007-2013 with several new initiatives. The European Research Council introduced a funding scheme to support investigator-driven frontier research across all fields, on the basis of scientific excellence[h]. The Innovative Medicines Initiative (IMI) set up public-private partnerships in health research[g]. Joint Programming Initiatives (JPI) were set up in 2008 to pool and integrate national research efforts in order to make better use of Europe's public Research and Development (R&D) resources and to tackle common European challenges more effectively in a few key areas. They were designed to overcome the fragmentation of national research programmes, via alignment and research funding, and to create a common research agenda, e.g. in antimicrobial resistance (AMR) and neurodegenerative research. JPI have a bottom-up approach and research topics are not pre-selected. They require a high-level commitment from Member States and are part of the ERA-NET Cofund instrument that regrouped all ERA-NET actions under H2020. The management board involves each member country. Funding is from MS and limited funding is provided by the EC FP. The Member States agree, on a voluntary basis, on a common research program to address challenges.

2014 - 2020: H2020

The Horizon2020 framework program (H2020) was launched in 2014 and will finish in 2020. A 2016 review of ERA-Net Cofund and JPIs by an appointed expert panel noted that significant issues are being addressed that are beyond the scope and resources of individual countries.[f,f] However, it was also noted that the instrument has limited impact on policies and that its potential is not realized.

[e] http://www.europarl.europa.eu/RegData/etudes/IDAN/2016/579097/EPRS_IDA(2016)579097_EN.pdf
[e] http://ec.europa.eu/research/era/partnership_en.htm
[f] http://ec.europa.eu/research/era/joint-programming-documents_en.htm
[g] https://www.imi.europa.eu/about-imi
[h] https://erc.europa.eu/

Appendix 3. Case studies of strong EU programs

Here a few examples are presented of programs in the health area, and by nature this list is limited and non-exhaustive. The aim is to illustrate a few different types of stakeholder involvement and of evolution of programs.

Innovative Medicines Initiative

The Innovative Medicines Initiative (IMI, www.imi.europa.eu) is one of five Joint Technology Initiatives, and is the world's biggest public-private partnership (PPP) in the life sciences. The aim of IMI is to improve health by speeding up the development of, and patient access to innovative medicines, particularly in areas where there is an unmet medical or social need. IMI was launched in 2008 with projects focusing on specific health issues such as neurological conditions (Alzheimer's disease, schizophrenia, depression, chronic pain, and autism), diabetes, lung disease, oncology, inflammation & infection, tuberculosis, and obesity. Other projects focused on broader challenges in drug development like drug and vaccine safety, knowledge management, the sustainability of chemical drug production, the use of stem cells for drug discovery, drug behaviour in the body, the creation of a European platform to discover novel medicines, and antimicrobial resistance.

The IMI 2 program, launched in 2014 and running for 10 years, will build on the successes and lessons learnt under IMI's first phase, and is intended to provide Europeans, including the increasing numbers of older people, with more efficient and effective medicines and treatments. Cost savings will ease the burden on public healthcare systems, and greater coordination across industry sectors will result in more reliable and faster clinical trials, and better regulation.

Analyses of the results of IMI projects highlight the benefits of this way of working: tracking the citation index of research papers coming out of IMI projects reveals that the citation impact of IMI papers is twice the world average and significantly higher than the EU average. In addition, a study of the selected projects' outputs found that IMI projects are generating products and knowledge that could prove valuable from a business point of view as well as direct health impact.

- In 2014, during the Ebola epidemic in West Africa, tens of thousands of people became infected with the disease and thousands were killed. Under difficult circumstances, IMI's EBODAC project set out to develop a community engagement and communications strategy to help IMI's EBOVAC1 project conduct a large clinical trial to test a promising new Ebola vaccine regimen and is followed by new programs to speed up clinical vaccine development.
- The IMI EUROPAIN project led to Europe having a stronger position in understanding nerve pain, and it has also triggered more research activity – a number of new projects are building on the EUROPAIN results.
- By bringing together the largest existing databases and biobanks on diabetes complications, the IMI project SUMMIT identified important soluble biomarkers which will help speed up the development of new medications. In the long-term, this could help patients have access to treatments earlier and lead to the development of better and more personalized medicine. Biomarkers are an important area for IMI to develop personalizd medicine, building on registries and biobanks as in BIGDATA@Heart.
- The IMI project SAFE-T focuses on new biomarkers that allow detection of drug side-effects earlier and

more accurately than in the past and is alos linked to other initiatives on drug safety.

Antimicrobial resistance

The EU has also played an important role in the fight against antimicrobial resistance (AMR). The activity in AMR is special and powerful as it has engaged different DGs within the EC, built on strong partnerships of EC and member states, and generated a global awareness and collaboration.

- A campaign in Belgium and France over antibiotic misuse (2000-2002) would not have been possible without an EU-funded project that collected necessary and highly compelling data on the scale of the problem. Both campaigns led to crucial decreases in antibiotic use and resistance among non-hospitalized patients. Furthermore, EU-funded, independent studies have demonstrated how the campaigns produced positive changes in clinician- and patient attitudes and behaviour towards antibiotic use.
- Inspired by the success of the antibiotic misuse campaign, the European Commission lent its support to the first European Antibiotic Awareness Day in 2008. This became an annual event, and in 2015 was scaled up to become the World Antibiotic Awareness Week, now coordinated by the World Health Organization.
- An IMI project concerning antimicrobial resistance, New Drugs for Bad Bugs or ND4BB (https://www.imi.europa.eu/content/nd4bb), aims to combat antibiotic resistance in Europe by tackling the scientific, regulatory, and business challenges that are hampering the development of new antibiotics.
- EU funding has enabled a comparison of antibiotic resistance in many hospitals throughout Europe. A project identified huge differences between countries in the proportion of infections that were resistant to antibiotics. The data provided a call to arms for many policymakers in member states, and national plans were rolled out for the first time to address the crisis. These initiatives have resulted in a notable reduction in infections caused by the superbug MRSA in hospitals throughout Europe.
- EU grants have supported the investigation of antibiotic use in food-producing animals in Europe. Findings illustrated that the Netherlands was one of the highest European users of antibiotics in farming. After a debate in the Dutch parliament, the Dutch minister of agriculture set mandatory targets for reduced antibiotic use in animal husbandry. Dutch farmers achieved these ambitious reductions ahead of schedule and there are clear indications that antibiotic resistance is decreasing in animals in the Netherlands. As food and associated resistant bacteria cross national borders, this increase in meat safety has benefitted Dutch consumers as well as consumers throughout Europe.

Cancer Core Europe

Cancer Core Europe (CCE) builds upon the efforts of previous European consortia such as the Eurocan Platform that was funded by the European Commission under FP7. CCE members, supported through member states, have engaged in a mission to reshape the cancer research model. The aim is to conduct cutting-edge research that is effectively translated to the clinic and will deliver more personalized medicine.

CCE can pave the way for a multi-site cancer institute in Europe for development of new treatments and earlier diagnoses for patients and more effective cancer prevention for Europe's citizens. Towards this end, an innovative approach will be taken to*

- sharing genomic and biological marker data as well as clinical and imaging data, then developing predictive modelling by mining this shared data,

- developing biomarkers (e.g. immune markers) and clinical imaging technologies to predict response to therapy,
- running cutting-edge clinical trials across all six centres with harmonized procedures,
- training the future generation of researchers and clinicians.

*https://www.cancercoreeurope.eu/who-we-are/

Biobanking and Biomolecular Resources Research Infrastructure

http://www.bbmri-eric.eu/BBMRI-ERIC/about-us/

In 2008, Biobanking and Biomolecular Resources Research Infrastructure, BBMRI, was one of the first projects entering the European Research Infrastructure Preparatory Phase of the ESFRI roadmap funded by the European Commission, lasting for 3 years until January 2011. At this time, BBMRI had grown into a 54-member consortium with more than 225 associated organisations (largely biobanks) from over 30 countries

The BBMRI was awarded ERIC Legal Status on 3 December 2013 in an agreement between member states under the specific EC Council Regulation. BBMRI-ERIC is a distributed research infrastructure in European Member States. Currently 19 Member States and one International Organisation are involved, making it one of the largest research infrastructures in Europe. The new status is facilitating the joint establishment and operation, bringing together biobanks and biomolecular resources into a pan-European facility and providing access to collections of partner biobanks and biomolecular resources, their expertise and services on a non-economic basis.

Appendix 4. Scientific Panel for Health members

Chair

Karin Sipido (BE)	Professor, Chair of Experimental Cardiology, Department of Cardiovascular Sciences, KU Leuven

Members

Fernando Antoñanzas (ES)	Professor of Applied Economics, University of La Rioja
Jean-Yves Blay (FR)	Professor of Medical Oncology, Head of Medicine Department, Lyon Cancer Centre
Martin John Buxton (UK)	Emeritus Professor, Health Economics Professor, Brunel University
Laurent Degos (FR)	Professor of Medicine (Hematology), University Paris VII
Jose Ferro (PT)	Professor, Chief of Department of Neurology, Lisbon University
Valentin Fuster (ES)	Physician-in-Chief, The Mount Sinai Medical Hospital Director, Mount Sinai Heart; Director of the Zena and Michael A. Wiener Cardiovascular Institute and the Marie-Josée and Henry R. Kravis Center for Cardiovascular Health Richard Gorlin, MD/Heart Research Foundation Professor Mount Sinai Health System; General Director of the Centro Nacional de Investigaciones Cardiovasculares Carlos III (CNIC)
Catherine Sautes- Fridman (FR)	Professor of Immunology, Head of Cancer, Immunology and Immunopathology Department, Paris Descartes University
Steffen Gay (CH)	Professor, Center of Experimental Rheumatology, University Hospital of Zurich
Hans Hofstraat (NL)	Vice President Philips Research, Healthcare Strategic Partnerships
Stephen Holgate (UK)	Medical Research Council; Clinical Research Professor of Immunopharmacology, Southampton University
Ildiko Horvath (HU)	Professor, Strategic Director, National Koranyi Institute for Pulmonology
Gabriel Krestin (NL)	Professor and Chairman of the Department of Radiology, Erasmus Medical Centre, Rotterdam
Frank Luyten (BE)	Professor, Head of the Division of Rheumatology, University Hospitals Leuven; Director Skeletal Biology and Engineering Research Center & Clinical Director, Stem Cell Institute, KU Leuven.

Michael Manns (DE)	Professor and Chairman of Department of Gastroenterology, Hepatology and Endocrinology, Hannover Medical School
Françoise Meunier (BE)	MD, PhD, Fellow of the Royal College of Physicians; Director Special Projects of the European Organisation for Research and Treatment of Cancer.
Wolfgang Oertel (DE)	Professor and Chairman of Department of Neurology, Philipps University Marburg
Susanna Palkonen (FI)	Director, European Federation of Allergy and Airways Diseases Patient Association
Dainius Pavalkis (LT)	Professor of Surgery, Lithuanian University of Health Sciences; Head of Innovation and Development, Kaunas Clinics; Provost of the Kazakh National Medical University
Helga Rübsamen-Schaeff (DE)	Professor Biochemistry & Virology Franfurt University; Chair of the Scientific Advisory Board, AiCuris GmbH & Co KG; Member of the Supervisory Board Merck KGaA, Member of the Board of Partners of E.Merck KG and Chair of its Research Council
Tomas Salmonson (SE)	Chair of Committee for Medical Products for Human Use, European Medicines Agency
Ulf Smith (SE)	Vice Chairman, Department of Molecular and Clinical Medicine, The Sahlgrenska Academy, Göteborg University
Bente Merete Stallknecht (DK)	Professor, Department of Biomedical Sciences, University of Copenhagen
Tuula Marjatta Tamminen (FI)	Professor of Child Psychiatry, University of Tampere; Chief Medical Officer, Child Psychiatry, Tampere University Hospital
Tomáš Zima (CZ)	Rector of Charles University, Prague

Advisors, with Special Role of Liaisons to the Scientific Community

Julio Celis (DK)	Associated Scientific Director, Danish Cancer Society Research Center
Richard Frackowiak (CH)	Professor at Ecole Politechnique Federale de Lausanne & CHUV University Hospital - Université Lausanne and Co-director of the Human Brain Project
Detlev Ganten (DE)	President, World Health Summit, Chairman of Board of Trustees Charité Foundation, Max Planck Institute of Molecular Plant Physiology

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Glossary

AMR	Antimicrobial resistance
CCE	Cancer Core Europe
DG	Directorate-General
DG Connect	Directorate-General for Communications Networks
DG RTD	Directorate-General for Research and Innovation
DG SANTE	Directorate-General for Health and Food Safety
EC	European Commission
EDCTP	European Developing Countries Clinical Trials Partnership
EEC	European Economic Community
EFTA	European Free Trade Association
EORTC	European Organisation for Research and Treatment of Cancer
ERA	European Research Area
ERA-NET	European Research Area Network
ERC	European Research Council
ERN	European Reference Networks
ESIF	European Structural and Investment Funds
ESMI	European Society for Molecular Imaging
EU	European Union
EuHCR	European Council for Health Research
EUPATI	European Patients' Academy
FET	Future and Emerging Technologies
FP	Framework Programme
GPC	High Level Group on Joint Programming
HTA	Health Technology Assessment
H2020	Horizon 2020
ICT	Information and Communication Technologies
IMI	Innovative Medicines Initiative
IRDiRC	International Rare Diseases Research Consortium
JPI	Joint Programming Initiatives
JPIAMR	Joint Programming Initiative on Antimicrobial Resistance
JPND	EU Joint Programme on Neurodegenerative Disease Research
MS	Member States
NIH	National Institute of Health (USA)
ND4BB	New Drugs for Bad Bugs
PM	Precision Medicine
PPP	Public Private Partnership
P2P	Public-to-Public (partnership)
R&D	Research and Development
R&I	Research and Innovation
SPH	Scientific Panel for Health