EU HEALTH COALITION

A SHARED VISION FOR THE FUTURE OF HEALTH IN EUROPE

TOWARDS AN EU HEALTH UNION

It's time to think big!

The EU Health Coalition proposes that health and the life sciences be recognised as a third strategic pillar for Europe in addition to the green and digital transition.

The EU Health Coalition's vision is of a Europe where health and care systems are centred on people and patients. We long for a Europe that takes a life-course approach to health - with a strong **focus on health promotion, disease prevention and overall well-being** - as well as on advancing the treatment, management, and cure of diseases. We want a system that works to **address unmet health and medical needs** and fights every day to **reduce health inequalities** across society. We envision modern services **anchored in a value- and outcomes-based approach** to health system organisation, financing, and management.

This **vision is shared by the people that make up European health and care systems**, as well as those who use these services. It is bold and ambitious, but it is more than a distant dream. We believe it can be achieved and propose concrete actions to drive Europe forward.

Through the unprecedented challenges during the last few years, we have learned that real, lasting change is possible. This lesson was learned the hard way but cannot be forgotten. The COVID-19 crisis demonstrated the fundamental role that health plays in the well-being of individuals and families, and of our societies and economies. The pandemic also left another legacy: by testing our systems to the limit and inspiring collective action in the face of shared challenges, it has made a compelling case for a stronger role for the EU in health. That is why the EU Health Coalition supports the development of an "EU Health Union". **This underpins our call for the consideration of public health and the health sector in all EU policies.**

Today, as Europe faces a geopolitical and energy crisis, with rising inflation and a looming recession creating new challenges for Member States, we should remind ourselves that **health is wealth**. **Our health systems are precious assets which we must nurture and protect.** Instead of putting additional burdens on systems that have been strained to the limit by COVID-19, **we must continue to invest in health and in the resilience of our systems**. Informed by experience of the past and the problems of the present, it is time for Europe to prepare our health systems for a brighter future.

Together, we are shaping the future of healthcare.

To deliver this vision, **the EU Health Coalition proposes the following recommendations and policy asks to EU policymakers.** We believe these are practical and balanced, bold, and achievable. It is our strong shared view that all EU actions should take account of equity in their implementation, including in relation to age, socio-economic status, gender, sexual identity, and ethnicity.
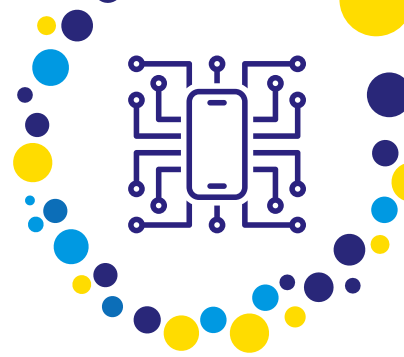
DIGITAL TRANSFORMATION

The opportunities offered by data and digital health are multiplying. While there are barriers to unlocking the full potential of these tools and technologies, we are at an unprecedented moment of change. The pandemic proved the value of digital health tools and demonstrated the need to catalyse the transformation. It provided patients and healthcare professionals with a chance to experience how technology can complement the expertise of clinicians while empowering service users. At the same time, the political momentum required to deliver lasting change is building.

Europe is implementing its strategy for data. Key EU policies,[1] including the European Health Data Space (EHDS), provide an opportunity to shape a data and digital ecosystem that can accelerate the shift towards patient-centred, outcomes-focused and sustainable healthcare in Europe, as well as improve patient safety and reduce avoidable harm. New and emerging legislation has the potential to enable better measurement of health outcomes, empower patients and create new ways of communication between health care professionals and patients. If successful, the EHDS will enable exchange of data across the full continuum of care and unlock new insights in healthcare, leading to a healthier society.

To quote the Commissioner for Health and Food Safety, Stella Kyriakides, 'the European Health Data Space is a fundamental game changer for the digital transformation of healthcare in the EU'. However, to realise this vision, we need to ensure that all aspects of the system are 'digital enabled'. This means working with policymakers, regulatory agencies, and healthcare providers to ensure we have the infrastructure, the data security framework, and the mindset required to capitalise on the opportunities that lie before us.

Health systems must be better connected. This will allow stakeholders to use health data for optimising and improving health outcomes. Interoperability is a critical enabler of the digital transformation of healthcare in Europe. This can be achieved by adopting interoperable quality and content standards, and by linking electronic health record systems and other sources of health data. It is paramount that common specifications are defined at an early stage of the proposed EHDS to avoid fuelling further fragmentation.

Digital healthcare is for all. Significant funding is required to close the digital divide between urban and rural communities, and to address the different levels of digital maturity of the Member States. Healthcare professionals and patients must be equipped with digital skills, while investment in infrastructure is essential. There will be no progress without people: generating greater trust is central to the success of the digital transformation. The EU must invest in campaigns on the benefits of data sharing and digital health. It is essential to engage with the public and stakeholders on the role of digital technologies and data, along with AI-driven tools, as a feature of trusted, accessible, affordable, and sustainable care. Together, we have an urgent responsibility to foster positive attitudes towards digital innovation.

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[1] Such as the European Health Data Space (EHDS) legislation and horizontal legislation (DA, DGA, DSA, DMA, NIS Directive, Cybersecurity Act, Cyber Resilience Act, Artificial Intelligence Act)

Recommendations and policy asks

1. Enable the collection of standardised, high quality and relevant health data in a secure manner to improve healthcare delivery, enhance research and drive greater efficiency of healthcare systems.

- In the **EHDS, define common specifications and standardised requirements** for data processing along with criteria for decision-making related to assessing applications for access to data across Member States. This would help to avoid fragmented implementation that would lead to fragmented rights. To truly enhance the flow and connection of data, and to minimise bureaucracy, **consistency with other data-related initiatives** (GDPR, AI Act, Data Governance Act, Data Act) is imperative.

2. Build a positive ecosystem fostering greater coordination and collaboration on Artificial Intelligence across the EU, and between different disciplines, to enhance the trustworthy and ethical use of AI in healthcare.
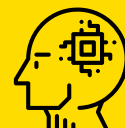
- **Invest in AI competencies and literacy as a key enabler of the European AI Strategy** that aims at making the EU a world-class hub for AI and ensuring that AI is human-centric and trustworthy. Ensure that the rules on AI laid out in the AI Act are adequate, appropriate, clear, and consistent, fostering a harmonised approach across the EU.

3. Invest in infrastructure, digital technologies, and skills development as crucial drivers to make digital transformation a success in the health sector.

- **Ensure appropriate financial support for the EU Member States** from the EU4Health programme and the Digital Europe Programme to accelerate the digital transformation. By offering tailored reskilling, lifelong learning and continuing professional development opportunities for healthcare workforce, establishing a robust data infrastructure and Electronic Health Records, and promoting the value of data and digital innovation, health outcomes can be improved for all.

- **Develop advanced digital skills for healthcare professionals** to support the safe and efficient use of digital technologies, as well as the collection and recording of patient data in electronic health records. **Ensure that citizens and patients have digital health literacy skills** to enhance their trust in, and understanding of, digital technologies to manage their health in an age, culture, and gender-inclusive manner.

HEALTH SYSTEMS INTEGRATION
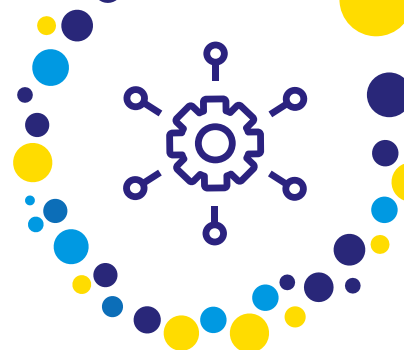
Integrating health systems has been at the centre of health policy discussions and research for a long time. However, the COVID-19 crisis clearly showed us how much remains to be done to achieve horizontal and vertical integration within and between our health systems. When we talk about health systems integration, we should **consider the different levels that integration in healthcare involves, and embed this in policy, research and healthcare organisation and financing efforts**. This should drive towards a more holistic approach aimed at delivering better care and improving quality of life. It is ultimately essential that people experience care continuity within health systems, equally, within Member States and across borders.

Integration also builds greater efficiency in the system thus delivering the best possible health outcomes using the human, financial, infrastructural, and technological resources available, with a focus on what really matters to individuals and to society. Improving efficiencies and reducing waste will benefit everyone – patients, carers, healthcare professionals, system managers, government, and industry.

As we are moving towards a European Health Union, a key pillar should be to enable health systems integration, while harnessing the opportunities offered by digitalisation. **Without achieving integration, Europe will struggle to deliver tangible improvements in patient care and quality of life**, through the individual EU health policy initiatives (e.g., the EHDS, Beating Cancer Plan, Healthier Together NCD Initiative). Nor could we expect meaningful success for the Health Union. Without integration, there is no union.

Recommendations and policy asks

4. Implement effective EU health policies and programmes coordination, within and across EU countries, to achieve health system integration.

- **Strengthen and measure the implementation of the Health in all Policies approach and ensure a broad health impact assessment:** all EU policies should be designed to be cross-beneficial, and their health impact should be clearly measured. Such measurement could be supported by a dedicated report of 'EU Health systems integration' in the 'State of Health in the EU' process and linked to the implementation of the Horizon Europe Partnership on Transforming Health and Care.

- **Foster coordination through multi-stakeholder partnerships** built on the quadruple helix model (science, policy, industry, society) and with proper engagement with regions and cities. In concrete terms, this could happen through the establishment of a European Health Union multi-stakeholder and multi-level (European, national, regional, local) advisory group, providing data and inputs on health systems and health policies integration challenges to EU institutions and Member States.

- **Elevate health workforce as a core pillar of the European Health Union,** building on existing and upcoming European-wide initiatives focused on future-proofing the European health workforce (e.g., BeWell project, HEROES Joint Action).

- **Move towards further improved cross-border cooperation,** building on the results of the evaluation of the Directive 2011/24/EU to ensure patients' rights in the EU in cross-border healthcare, tackling identified shortcomings (e.g., obstacles to reimbursement), further developing positive achievements (e.g., ERNs), recognising and supporting the central role of regional and local health authorities.

5. Incentivise integrated care across Europe through dedicated resources, competences development and assessment.

- **Support health systems in adopting incentives supporting concrete integration of care** and the development of integrated care patient pathways. This could be made possible, for instance, by

  - Researching and implementing innovative financing models, linked to value and outcomes, ensuring affordability, bridging of budget silos and delivery of better care.

  - Linking payments to outcome metrics to incentivise focus on high-quality service delivery, positive patient outcomes and quality of life.

  - Developing a European framework to assess implementation and progress on integrated care (through dedicated EU project) and the inclusion of an integration of care measure in EU projects proposals.

- **Boosting health professionals' integration and interdisciplinary skills.** Health systems integration elements should be better included in education and on-the-job training, by working with professional institutions to provide educational materials and opportunities on integrated care.

BOOSTING RESEARCH AND INNOVATION

The last several decades have seen huge advances in medical science, providing new treatments, prevention and even cures for previously untreatable diseases and continuous advances in the fight against cancer and many other chronic diseases. The COVID-19 crisis also proved the importance of having a vital innovation eco-system in Europe, to quickly develop, trial and manufacture at scale vaccines and other medical countermeasures. **But progress cannot be taken for granted, nor that Europe will be in the forefront of health research and innovation in the future.** Improvements in life expectancy and quality of life are the fruits of long-term dedication to scientific research and development and the application of new medical knowledge to deliver for patients.

We need to invest in making Europe a true research and innovation hub. With the new political environment and the risk of an economic downturn, EU policies must be futureproofed for health. Today's EU decision makers are building the research environment of tomorrow. Thus, we need to ensure that we have the right policy actions to develop an ecosystem that is conducive to health research, and to translate this research into innovative solutions that improve the health of people and patients. We need to build an ecosystem that sustains interdisciplinary networks, cross border initiatives, health data infrastructures, robust collaboration, partnerships, the vital role of innovative Small and Medium Enterprises (SMEs) and medical education while enabling regulatory flexibility.

Key EU policies and frameworks such as the Multiannual Financial Framework, the European Innovation Agenda, the European Health Data Space, the EU Pharmaceutical Strategy[2] and the European Industrial Strategy should support R&I. These instruments must be designed to ensure that research will take place in Europe and that EU citizens will benefit from a strong R&I ecosystem.

Recommendations and policy asks

6. **Invest in Europe as a true research and innovation hub, making sure that excellence in basic research and early discovery is translated into innovative solutions, products, and services through a strong public-private ecosystem.**

- **Focus investments through earmarked funds** in the next Multiannual Financial Framework (including through the structural funds and RD&I funds) to support vibrant and sustainable life science ecosystems and clusters at scale in Europe, strengthening all components including human capital, intellectual capital, growth, and innovation capital.

[2] Including the revision of the general pharmaceutical legislation as well as the Orphan and Paediatric Regulations.

- **Ensure that the next EU RD&I budget is ring-fenced** from the rest of the MFF to ensure funding instruments' stability and maintain trust in the system.

- **Ensure alignment between the EU Industrial and Pharmaceutical Strategies**, facilitating the translation of early scientific discoveries into innovative products and services in Europe through a vibrant life science sector – including Small and Medium-Sized Enterprises, supported by a competitive IP protection framework and a future-proof regulatory system.

- **Ensure an inclusive and patient-centric understanding of Unmet Medical Needs**, so that research and development of prevention, diagnostics, treatment, and cures aligns with patients' needs across disease areas and does not stifle the development of treatment options that improve patients' care and quality of life.

- **Ensure that sufficient research funds and incentives are in place to meet the needs of underserved populations and areas**, such as children and rare disease populations, including through EU research funds (e.g., through the Horizon Europe strategic planning process 2025-2027) and the revision of the Orphan and Paediatric Regulations.

- **Ensure that the EHDS can enable translational research, strengthen federated data networks, and access and use of RWE**. The new regulation must provide the necessary regulatory clarity and harmonisation around health data sharing, without adding additional complexity to a situation where legislation already overlaps, and national or local interpretations differ.

ACCESS TO INNOVATION

To achieve our vision for a healthier Europe, patients must be able to access and afford the treatment and care that they need when they need it. This includes innovative treatments and procedures based on the latest scientific, clinical, and technological advances. However, there are currently deep disparities in access to effective prevention, diagnosis, treatment, and care in Europe, both between and within countries, and unnecessary delays in the uptake and scaling up of new, evidence-based solutions in health systems.

Though most decisions on access to, and funding of, treatment and care are taken at a national or regional level, there are things the EU can do to support both patients and health systems. **We see opportunities for the EU to facilitate access to the latest advances in medical care and to improve health equity in the Union.** The EU can help to ensure that patients have a voice in healthcare prioritisation and delivery, and to improve the health literacy of patients and healthcare professionals. It can support the identification of inequities and bottlenecks and the sharing of best practices by measuring and benchmarking access to care, delivery of care and outcomes of care.

European policymakers will also have a central role in changing the way we think about health spending. Crucially, we need to **view healthcare as an investment** and to identify interventions that deliver measurable impacts. In all of this, sustainability, value, and the needs of the patient must be paramount.

Recommendations and policy asks

7. Monitor the development of new medical technologies and practices to allow for health system planning and early stakeholder awareness. Foster the uptake and spread of these technologies and practices in health systems to facilitate actions for health equity and improve health literacy.

- The EU should establish a **monitoring centre for innovative health technologies and clinical practices** in collaboration with Member States and stakeholders including patients, healthcare professionals and industry. The centre should perform:

  - **Horizon scanning of medical technologies in development**, to facilitate early health system planning for the introduction of health innovation and early stakeholder awareness.

  - **Monitor and benchmark uptake and spread of innovative clinical practices** (including the timely update and uptake of clinical guidelines as well as diagnostics and programmes for screening and early detection) **and access to new treatments and technologies** (including for children and rare diseases), in European health systems. This would support the identification of inequities in access to healthcare, including barriers and bottlenecks for healthcare professionals and patients to avail of innovative health solutions across the union. This action would also **improve health information and health literacy for all**, including for healthcare professionals, patients and informal caregivers, by making this information available.

  The monitoring centre could be set up as part of the Joint Research Centre, using EU4health funding.

8. Reframe healthcare expenditure that provides long-term value as an investment rather than cost.

- **The Commission and Member States should initiate a discussion on how certain healthcare expenditure could be classified as investment** rather than operational expenditure for the purpose of budgeting and accounting, to enable new forms of financing and funding models. The European System of Accounts should be reviewed and adapted for this purpose.

9. Support the development of patient-centric and outcomes-based health systems.

- **Support Member States in adopting national plans for patient-centred health systems**, which should include modalities for patient engagement in healthcare decision making at all levels of healthcare (macro, meso and micro), as well as actions to capture the voice of children, informal caregivers and underserved communities. Templates and methodologies could be developed through a dedicated EU4Health project and recommended to Member States through a Council Recommendation.

- **Set up sustainable frameworks for the collection of standardised measures** on 1) patient experience on access to, and process of, care to benchmark performance and guide policy action, and 2) patient health outcomes to allow patients to have evidence-based communications with healthcare professionals and health authorities whilst also allowing evidence-based decision making for health policy. The standardisation and collection of health outcomes data should build on the progress made by the IMI Health Outcomes Observatories PPP (H2O) and other relevant projects, providing a model for outcomes measurement standardisation, integration with other data sources and the use of outcomes data for healthcare delivery and research.

- **Review the EU cross-border healthcare directive** to include the disclosure of relevant indicators on access, process and health outcomes as part of information requirements, to enable informed decision-making by patients.

EU HEALTH COALITION

The EU Health Coalition is composed of 43 patient organisations, EU research-oriented medical societies, industry organisations, healthcare providers, regional and local health authorities and other relevant stakeholders, who all share a common vision.

To find out more about the work of the EU Health Coalition, please visit our website www.euhealthcoalition.eu

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