

The Guild's input to the call for evidence on the EU cardiovascular health plan

Research and innovation (R&I) are essential to maintaining public health in a rapidly changing society. As Europe's population ages, multi-morbidities become increasingly prevalent, particularly those affecting cardiovascular health (CVH). The Guild calls on the European Commission to develop a comprehensive EU Cardiovascular Health Plan, providing a coordinated EU-level response that leverages R&I across primary, secondary, and tertiary prevention, early detection, treatment, and long-term care. Below, we highlight key factors for a thriving European health R&I ecosystem in the field of CVH, which align with the key action areas as outlined by the European Commission.

Addressing the current research and innovation gap

As the European Commission has rightly pointed out, there is an urgent need to bridge the existing R&I gap in cardiovascular diseases (CVD) prevention, diagnosis, and treatment. Reliable and comparable data are crucial for developing high-quality health products. Still, the contribution of interdisciplinary and collaborative research across Member States, particularly that generated by academic researchers, is equally vital to advancing the goal of bridging the gap. This research needs to be further strengthened to increase our understanding of the incidence, prevalence, and progression of CVDs, leading to independent, evidence-based policy.

Furthermore, the potential of digital technologies, including Artificial Intelligence (AI), quantum, as well as virtual human twins and advancements in the field of organ-on-a-chip, contribute to advancing research in cardiovascular health. These technologies can enhance data collection, analysis, and interpretation, resulting in more accurate and personalised treatment approaches. At the global scale, facilitating research in, for example, the mechanistic and phenotypic differences of CVD between population groups can lead to more nuanced and context-appropriate treatment approaches. The latter being particularly important as more knowledge on women- and ethnicity-specific presentation and risk factors is needed.

As already noted in the European Health Data Space (EHDS) Regulation, the role of fundamental research is crucial for achieving long-term societal benefits. However, its benefits to end-users and patients may be less direct (Recital 61). As such, unlocked by the EHDS, fundamental research can make significant contributions, including activities related to cardiovascular genomics. This interdisciplinary field aims to understand the complex relationships between genetic variations and cardiovascular health.

The Guild welcomes the reference to the EU Life Sciences Strategy as a facilitator to address the current R&I gap and stresses the importance of an inclusive integration of the entire R&I ecosystem. Existing and future clinical trial networks and research infrastructures need to be further leveraged to accelerate the validation and deployment of innovative therapies and diagnostics. This requires collaboration with universities and public research organisations, as they play a central role from early-

stage discovery to trial design and execution. It is worth noting that some Member States have a clear R&I advantage, due to their level of R&I investment, leading to varying maturity levels of national infrastructures, including health registries, cohort size and epidemiological studies across the EU. Therefore, the Plan should emphasise the advantages of national health registries, cohort databases and epidemiological studies, to give the European Union a continued competitive edge in the field of cardiovascular research.

Prevention and early detection

The Plan needs to enhance public awareness and implement improved preventive strategies to facilitate early diagnosis and treatment, as most cardiovascular diseases can be prevented through, among others, the identification and management of risk factors. The Guild emphasises the importance of investing in interdisciplinary research to identify and characterise additional risk factors associated with CVD, including genetic, environmental, socio-economic, mental health, and lifestyle determinants, to, for example, address unhealthy behaviours. Significant advancements can be made when collaborating with disciplines such as the social sciences and humanities, nutrition and sport sciences, as well as genetics. Lastly, it is equally important to assess and evaluate existing guidance on health checks and screening protocols before establishing new ones, as well as those that support the uptake of digital health tools. Health policy and system research is, therefore, an essential component.

Health inequalities and inclusion

CVD disproportionately affects socioeconomically disadvantaged populations. The Plan must integrate equity considerations at its core, ensuring that prevention, screening, and treatment strategies are inclusive and equitable, by also improving access to innovative healthcare technologies and services in underserved communities. Anthropological and behavioural research is needed to inform evidence-based decision-making on why certain groups are more reluctant to seek healthcare than others and advise on what measures are required to overcome these barriers.

Supporting Member States and strengthening Europe's competitiveness

The EU's role in complementing national actions will provide significant added value when facilitating the implementation of existing EU legislative and non-legislative initiatives. Focusing on, for example, the harmonising GDPR implementation, must alleviate existing bottlenecks, significantly facilitating research collaboration. The EU can provide a framework for coordination and cooperation among Member States, ensuring that best practices are shared and resources are optimally allocated.

While the EHDS, the AI Act and the forthcoming AI Strategy provide valuable references to the interplay of health data and AI, the Plan should also consider the upcoming revision of the EU Pharma legislation, which, depending on the final text, may include regulatory sandboxes. They will facilitate the development, validation and testing of innovative or adapted regulatory solutions in a controlled environment, contributing to the authorisation of innovative products. Additionally, the Plan should take into consideration the work being done by the European Reference Network (ERN), particularly ERN GUARD-Heart, which is the network for uncommon and rare heart diseases.

The Guild appreciates the European Commission's intention for the Plan to assist Member States in achieving the Sustainable Development Goals, particularly SDG target 3.4, which aims to reduce the

burden of non-communicable diseases, including cardiovascular diseases. Nevertheless, given the current global deficiency in achieving the objective of reducing premature mortality from non-communicable diseases by one third through prevention and treatment, and in promoting mental health and well-being, The Guild requests clarification on whether this plan alone will be sufficient to achieve the target within the remaining five-year timeframe and whether more long-term action is foreseen as part of the Plan.

Finally, the EU can only be as competitive as its population is healthy and able to contribute, a concept already reflected in the Council Conclusions on Economy of Wellbeing in October 2019, which claims that while people's wellbeing is a value in itself, it is also important for the Union's economic growth, productivity, long-term fiscal sustainability and societal stability.

The global perspective on cardiovascular health

A globally inclusive understanding of CVD is imperative for Europe, as it would enable the identification of risk factors and inform the development of targeted interventions, particularly in remote areas. As such, the Global Health Strategy, published in November 2022, identifies helping prevent and manage non-communicable diseases as one of the EU's key global health priorities. The European Commission is employing multisectoral approaches that address key risk factors, including substance abuse, diet, physical inactivity, and air pollution. The Plan should align with this approach. In addition, the Plan should support the strategic vision of the African Union and European Union by aligning with the Global Gateway's Innovation Agenda and fostering collaboration within the integrated Africa-EU STI Programme.

Monitoring and implementation

The Plan's impact will depend on a robust monitoring and evaluation framework. The Guild calls for the inclusion of validated and internationally recognised research-based indicators, as well as the use of representative longitudinal datasets, to track health outcomes, innovation uptake, and reductions in inequalities. The Guild notes that the Plan should consider the findings of the implementation and evaluation plans of the European Beating Cancer Plan and apply lessons learnt. Further, objectives and goals established in the plan must be explicitly articulated, incorporating specific, measurable, attainable, relevant, and time-bound criteria.

Lastly, the monitoring framework should include transparent governance and structured engagement with academia, healthcare providers, industry, and patient organisations to ensure effective implementation.