each
European Alliance for Cardiovascular Health

A European Cardiovascular Health Plan: The need and the ambition

CONTENTS

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EXECUTIVE SUMMARY

This document sets out the ambitious vision of the European Alliance for Cardiovascular Health (EACH)[1] to address the huge burden of cardiovascular disease – Europe's biggest health challenge. It outlines proposals for a dedicated EU Cardiovascular Health Action Plan and Cardiovascular Health (CVH) Mission to commence at the beginning of the next political mandate. The proposals are inspired and informed by the on-going success and impact of the European Beating Cancer Plan and Mission.

EACH welcomes the "Healthier Together" initiative on Non-Communicable Diseases (NCDs), which, for the first time at European level, creates an important platform to address NCDs. There is, however, strong evidence of an imperative need for a dedicated singularly focused CVH plan that covers the entire spectrum of cardiovascular health during the life course. "Healthier Together" is an important springboard to help to achieve this, during the current mandate, through Joint Actions on Cardiovascular Diseases and Diabetes, and a proposed Joint Action on early detection.

EACH believes the overall vision for a future CVH plan should be:

By 2030, premature and preventable deaths in Europe from CVD related causes will be reduced by one third, in line with the Sustainable Development Goal Target 3.4. Every person living in Europe will have access to high quality cardiovascular risk assessments throughout the life course, and all CVD patients will have access to a care pathway that focuses on their needs and goals.

A European CVH plan should therefore focus on:

- **primary prevention[2] to decrease premature mortality and morbidity at population level**, to identify the most effective policies and measures to reach out and manage individuals at high risk of developing CVD and pilot these specifically as part of CVH National Action Plans.
- **secondary prevention** through timely screening, early detection, and precision diagnosis, creating a **European Cardiovascular Health Check**
- **early intervention, access to quality, personalised healthcare**, including innovative and precision care solutions building on evidence from basic and translational CV research to better understand the molecular causes and mechanisms of CVD.
- **rehabilitation**, by establishing a **network of experts** to agree a common definition, identifying barriers and opportunities for the **uptake of cardiac and stroke rehabilitation** building on the Stroke Action Plan for Europe, supported by digital health solutions.
- **quality of life and other psychosocial outcomes** across the spectrum

of cardiovascular diseases by creating a **European patient-relevant standardised instrument, measuring quality of life and other PROMS** related to it, reinforcing the role of **patient organisations** in quality of life and long-term care, and addressing **survivors' and their families' long-term unmet needs** through minimum standards.

Dedicated flagship actions should be included in and across each of these pillars.

Cross-cutting actions should comprise:

- **a European CVH Knowledge Centre** to address the current fragmentation and significant gaps in **reliable data and ensure connectivity across the spectrum of CVD** and related conditions and cross border collaboration.
- **a European Cardiovascular Health Observatory** to capture important developments in all areas of cardiovascular health in Europe, highlighting **beacons of excellence**, and how these could be **replicated and scaled across Europe**.
- **national CVH Action Plans** to reflect the national context and culture and provide an essential **framework for national implementation** of a European CVH Plan with appropriate emphasis, investment and targets on primary, secondary and tertiary prevention.
- **an incubator and progressive policy environment for digital transformation** in CVH to help **facilitate innovation, trust and equitable uptake of digital health solutions** across the CVH community across Europe.

A CVH Mission should be established, spearheading research and innovation to support the CVH Action Plan, mirroring the Beating Cancer Plan and Cancer Mission. Basic and translational cardiovascular research is crucial to improving understanding of the molecular causes and mechanisms of CVD in order to develop high-performance diagnostic tools, targeted strategies for personalising treatment and management, and to develop new medicines. The CVH Mission will place major emphasis on the translation of research outcomes and evidence into CVH policy and implementation at national level.

Pragmatic and well-conducted randomised clinical trials are the bedrock of safe, effective and evidence-based treatment of CVD. However, the cost and complexity of clinical trials in CVD have increased disproportionately. A dedicated CVH Research Mission will facilitate an enabling environment for CVH Clinical Trials and deeper collaboration across the CVH multistakeholder community.

A series of topics have been proposed by EACH for this new CVH research agenda.

Over the next two years, the European Commission, in building a European CVH Action Plan, is invited to:

- engage all relevant players to garner universal support from the EU Member States, regional governments and all relevant stakeholders representing the CVH community
- undertake a European Impact Assessment

- support foundational work linked to the implementation of Healthier Together on CVH
- learn from the Joint Action on CVD and Diabetes
- launch a public consultation, including citizens' juries
- organise multi-stakeholder workshops on learnings from COVID
- convene a dedicated taskforce on the implications of major health threats, such as climate change or the war in Ukraine, on a future plan.

The success and impact of a European CVH Plan will be shaped not only by what is achieved over the next few years, but also by how it is achieved, leaving no-one and no country behind. The Plan must address societal barriers, underserved populations, discrimination on all grounds, and fundamental inequalities pervading health systems across Europe.

Several important considerations for the architecture of the Plan are proposed, including a life course perspective, inclusive governance, synergies with other relevant EU instruments and initiatives, agile innovative Public Private Partnerships, institutional collaboration in the context of the wider Europe, and global advances on cardiovascular health.

EACH Partners agreed this proposal for a dedicated European Cardiovascular Health Plan and CVH Mission and a strategy for EACH, at the end of April 2022. All EACH partners are committed to working together to deliver this ambition, and to support the European Union in playing its vital role in addressing the burden of CVD and the biggest health challenge facing its people and fragile health systems across Europe.

INTRODUCTION AND CONTEXT : TRANSFORMING THE NARRATIVE FROM DISEASE TO HEALTH, FOR PATIENTS AND PEOPLE

The purpose of this document is to set out the ambitious vision of the European Alliance for Cardiovascular Health to address Europe's biggest health challenge, namely the huge burden of cardiovascular disease on people and on systems through a dedicated European Cardiovascular Health Action Plan and Mission. It includes proposals for the main pillars for such a plan and how they might be crafted.

This is set in the context of a "new" Europe, in health terms. As we emerge, slowly, from the COVID-19 crisis, we recognise its wake-up call for transforming health systems and public health across the Union. We see clear evidence of how patients living with, and people at risk of cardiovascular disease have been disproportionately affected, and the long-term catastrophic impacts of this. We see the ravages of war in Ukraine with huge, immediate health implications

within the country, the influx of people, mainly women and children seeking refuge, and the many long-term health unknowns linked to this tragedy, which will also impact on future cardiovascular health in Europe. We also see the enormous challenges of climate change and environmental conditions that will profoundly affect our lives.

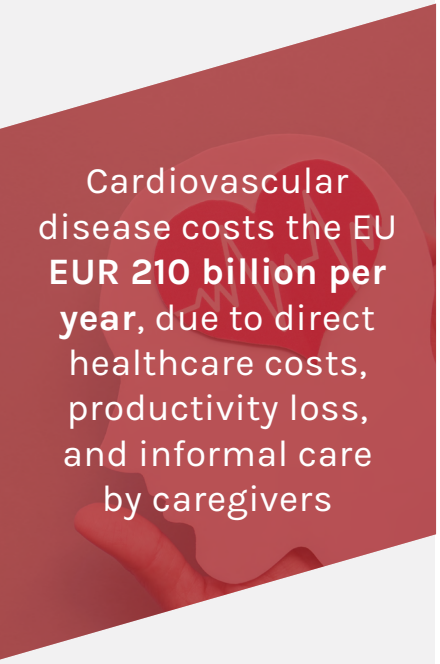
Digitalisation of health and an increasing understanding of the value of health data are prominent on health agendas everywhere, as key levers to improve outcomes for patients and communities.

There is now the imperative and means to do things differently at European level, to create new multi-stakeholder partnerships and allegiances, to be agile, bold and resourceful in the journey towards a European Health Union that reflects the needs and the goals of Europe's patients and people.

The cardiovascular disease world is also changing, with increasing recognition that it is everybody's business - it can affect anyone, at any age. Not all cardiovascular diseases are the same and require different approaches, however, we are moving from looking at the condition to the person – from cardiovascular disease to cardiovascular health, for patients and people, through primary, secondary and tertiary prevention[3]. This is an important shift and is the bedrock for our call for a European Cardiovascular Health Plan.

The time for action is now. The evidence is clear – the unbearable burden of cardiovascular disease for patients, people, health systems and society in Europe will only increase if we do not channel enormous political will, leadership, expertise, and imagination and create a different future landscape for cardiovascular health in Europe.

> ***While premature CVD onset could be prevented or postponed in many cases and excellent drugs and devices are available, CVD morbidity and mortality have remained concerningly high and causal therapies enabling a better precision in CV care are largely missing. In addition to awakening the political/societal will to tackle this serious health challenge, we need a paradigm shift in how the stakeholders are currently engaging. All stakeholders need to engage in new ways to tackle cardiovascular health – policy makers/payers, industry, the clinical community and patients need to work together in ways they have never done before***
>
> EACH Patient Representative



THE BURDEN OF CARDIOVASCULAR DISEASE IN EUROPE

Cardiovascular disease can affect anyone. **CVD knows no gender, no age**. CVD can also be triggered by other chronic conditions or their therapies

Around **20% of all premature deaths** (before the age of 65) in the EU are caused by CVD

Tremendous inequalities remain in patients' access to appropriate cardiovascular care within and between EU countries

Cardiovascular disease (CVD) is a group of disorders, all related to the heart and circulatory (vascular) system[4]. Past efforts and investments into better cardiovascular care, combined with improvements in preventative strategies and infrastructure for acute care, have resulted in a substantial reduction of CVD mortality over the past 50 years. Nonetheless, cardiovascular events (mainly heart attacks and strokes)[5] remain by far the **leading cause of death** in the European Union (EU).[6]

In the EU, CVD accounts for **36% of all deaths** and profoundly impacts the lives of **some 60 million people** who are living with CVD[7]. Furthermore, the reduction in CVD mortality has started to plateau and, in some countries, mortality has even started to increase. This should be a cause of great concern for policymakers at all levels, when considering population health and the effect on health systems.[8]

Cardiovascular disease is not limited to older people. Quite to the contrary, it heavily **impacts people of all age groups**. Around **20% of all premature deaths** (before the age of 65) in the EU are caused by CVD. The fundamental misperception of CVD is a major challenge. It is seen very often as a "lifestyle" disease only. While major efforts are, of course, needed on prevention, we also need bold actions to target all age groups at risk.

Many conditions, such as familiar hypercholesterolaemia (FH)[9], are inherited and are related to non-modifiable risk factors[10], and some conditions may not manifest themselves until adulthood. People can also be born with heart disease. The prevalence of congenital heart disease is predicted to increase in the next 20 years.[11]

The risk and prevalence of CVD increase even further with age and unpreventable functional decline. This is of utmost relevance in view of **Europe's ageing population**. In 2040, 155 million Europeans will be over 65 [12]. Without decisive action starting today, the number of citizens suffering from CVD and the burden of dealing with the disease will increase dramatically for societies and for health systems alike. For example, the projected number of people living with stroke will increase by 35% (from nine million in 2017 to 12 million in 2040) [13].

It is important to stress that people who have experienced a CVD event, such as stroke, or heart attack, remain at high risk of another CVD related event, and need timely, on-going quality care and long- term support. The far-reaching personal, psycho-social impacts for them and their families are enormous.

CVD often is triggered by other chronic conditions or their therapies[14], including but not limited to, diabetes, hypertension, chronic kidney disease, pulmonary disease, and cancer, referred to in this document as 'NCDs'.

Timely identification and appropriate management of these **comorbidities** are essential to combat cardiovascular disease and to reduce healthcare costs.

Reducing inequalities is at the heart of EU action on health, but this is far from being achieved in the context of CVD. There are many unmet needs and underserved communities, including refugees. **Huge inequalities** in the access to appropriate cardiovascular care, often due to social and economic disparities, persist within and between EU countries. Death rates from CVD are higher in Central and Eastern Europe than in other parts of Europe. For example, the age-standardised death rate for heart disease is 13-fold higher in women in Lithuania than in France, and 9-fold higher in men. For stroke, the age-standardised death rate is 7-fold higher in women in Bulgaria than in France, and 8-fold higher in men[15]. These inequalities, resulting in major differences in access, awareness, and outcomes should be urgently addressed.

Cardiovascular disease costs the EU **EUR 210 billion** per year, due to direct healthcare costs, productivity loss, and informal care by caregivers[16]. Certain CVDs (e.g. heart failure) are a major cause of hospitalisation and place significant pressure on fragile health systems[17]. The **COVID-19 pandemic** has added to this challenge due to the significant impact on CVD patients, in terms of access to, and delivery of care, as well as of heart health and cardiovascular complications[18]. Indeed, data shows that pre-existing cardiovascular conditions are particularly important predictors of COVID-19 severity and mortality.[19] [20] [21]

Strengthening and improving the resilience of healthcare systems to pandemics requires acting decisively to improve cardiovascular health. COVID-19 has brought to light the **high vulnerability of CVD patients**[22] and that reducing the burden of CVD and other chronic conditions is the best way of making the European population more resilient to future health threats.

EACH'S AMBITION FOR CARDIOVASCULAR HEALTH IN EUROPE: SHAPING 'HEALTHIER TOGETHER' AND THE CARDIOVASCULAR HEALTH PLAN AND MISSION

EACH calls for a dedicated Cardiovascular Health Plan and Mission **alongside** the Healthier Together NCD initiative, which reinforces the Cardiovascular Health Plan agenda.
EACH welcomes the European Commission's Initiative 'Healthier Together' which, for the first time at European level, creates a platform for Non-Communicable

Diseases, including CVD, and builds on the flagship actions of the Beating Cancer Plan. The scene is set for deeper collaboration and progress on primary prevention, common risk factors, genetic variables, molecular causes, role of comorbidities, including piloting the implementation of novel approaches derived from research, and the political, environmental, social, and commercial determinants of health through concerted, collaborative efforts. "Healthier Together" will also provide a much-needed political focus on important legislation and soft policy in the areas of food and nutrition, smoking, alcohol, physical activity, and air pollution[23], and importantly, its implementation at national level.

We see the great potential of 'Healthier Together' to contribute, through the lens of NCDs, to strengthening health systems and addressing unacceptable health inequalities within and across EU countries.

"Healthier Together" will also contribute to building resilience and crisis preparation, recognising that people living with NCDs are invariably and profoundly affected by crises, be they humanitarian, financial, and/or health related.

"Healthier Together" underlines how critical it is to prevent the onset and progress of CVD with population-wide interventions, secondary prevention approaches and programmatic screening of specific groups as well as investing in innovation derived from basic and translational research.

Given the enormous burden of cardiovascular diseases on patients, on people, and on European societies and economies as described earlier in this document, a **dedicated Cardiovascular Health Plan and CVH Mission** is also vital to achieve the outcomes the EU Institutions, national governments, the scientific community, and civil society aspire to, to address Europe's biggest health challenge and number one killer.

The Beating Cancer Plan and Cancer Mission are demonstrating the huge impact of a singular, highly focused approach and are an important precedent both in terms of this approach, and in terms of budget.

A dedicated European Cardiovascular Health Plan should be complementary to the 'Healthier Together' initiative, addressing common NCD risk factors, health determinants and ways to advance CV research and care.

EACH believes the overall vision for a future CVH plan should be:

By 2030, premature and preventable deaths in Europe from CVD related causes, will be reduced by one third, in line with the Sustainable Development Goal Target 3.4. Every person living in Europe will have access to high quality cardiovascular risk assessments throughout the life course, and all CVD patients will have access to a care pathway that focuses on their needs and goals.

A European CVH plan should therefore focus on:

- primary prevention[24] to decrease premature mortality and morbidity at population level.
- secondary prevention through timely screening ,early detection, and diagnosis.
- early intervention, access to quality health care, including innovative and precision medicine. Early intervention approaches should be based on findings from basic and translational CV research aimed at better understanding the molecular causes and mechanisms of CVD. rehabilitation and long-term care.
- quality of life and other psychosocial outcomes across the spectrum of cardiovascular diseases.

Dedicated flagship actions in and across each of these pillars should be included in the Plan.

Synergies should be created with plans in specific disease areas[25], where they exist, and the European Beating Cancer Plan, to ensure mutual reinforcement, coherence and non-duplication of efforts.

DEVELOPING THE EUROPEAN CVH PLAN IN THE SHORT-TERM

During the next two years, we propose that the European Commission:

- ensures the widest possible geographic representation and commitment by involving all stakeholders, including the Member States, regional governments, healthcare professionals and providers, insurance organisations, patient and citizens' organisations, researchers and industry in the planning, implementation, governance, and evaluation mechanisms of a European CVH plan.

- undertakes a European Impact Assessment to prioritise action and policy instruments in each of the five pillars of the European CVH Plan, building on experience learned from the Beating Cancer Plan and existing best practice, such as Swedeheart[26], young50[27], and ERA-CVD[28].

- invests in foundational work on the implementation of "Healthier Together", through current funding mechanisms, notably the EU4Health Programme, the establishment of a Joint Action on Cardiovascular Disease and Diabetes and a proposed Joint Action on Early Detection, using experience from these to inform the European CVH Plan and its five core elements described above.

- allocates funding to preparatory initiatives, with a top -down, bottom-up approach. EU4Health can support co-ordinated EU actions, whilst the Recovery and Resilience Funds can invest in specific activities at national and regional levels.

- holds a public consultation, complemented by a European public awareness/ education campaign on CVH, and 'citizen juries' at national level, to craft the CVH plan, grounded in grass-roots needs and experience, in understandable and relatable language.

- convenes a series of multi-stakeholder workshops to examine the key conclusions from the Covid-19 pandemic in a structured way, building on an emerging body of work, to understand the specific implications for cardiovascular health policy and practice at European level. This would include long-standing, deep-seated issues on which Covid-19 shone a harsh light, such as the importance of behaviour/ motivation information and communication management, vaccine, or 'prevention' hesitancy, mental health implications and the fear and specific vulnerability of patients living with CVD, and those at significant risk, as well as the links between CVD, Covid and Long Covid and the enormous treatment/ rehabilitation backlogs. These learnings should be integrated in the preparation of a CVH Plan, in the spirit of building a better future for patients and society at large and more resilient health systems.

We are facing major challenges that will significantly reduce public and CV health. Climate and adverse environmental changes including pollution will increase incidence and mortality due to CVD. The war situation in Ukraine persists, and the vast human and health impact in the country and on people seeking refuge in Europe is immeasurable at this juncture. A dedicated taskforce should be created to seek to understand the implications for a European Cardiovascular Plan moving forward.

PROPOSED KEY COMPONENTS OF A FUTURE CVH PLAN

HORIZONTAL, CROSS-CUTTING ACTIONS

European Cardiovascular Health Data Knowledge Centre

Echoing policy developments in the framework of the European Health Data Space, EACH calls for the creation of a "European Cardiovascular Health Data Knowledge Centre" to ensure appropriate infrastructure, interoperability, data protection, security and stewardship, bringing together existing registries, electronic health record platforms, patient and citizens' generated data and related initiatives in CVD in one large-scale action. This should address the current fragmentation and significant gaps in reliable data and ensure connectivity across the spectrum of CVD and related conditions and cross border collaboration.

The goal would be comprehensive and standardised data to support strengthening the health system, innovation, research, person-centred value-based decision-making, investment in cardiovascular primary and secondary prevention, risk stratification, personalised prevention and treatment, and integrated data-driven care pathways focussed on the needs and goals of the patient.

The CVD Health Data Knowledge Centre will be the source and reference point of reliable and trusted, state of the art, community-focused, evidence-based information on CVD and related conditions, thus challenging existing low quality, non-curated, possibly misleading information.

This Knowledge Centre could also monitor patients' access to quality CV care across the entire patient pathway, including long-term care, and would enable country level comparison, scorecards, and advocacy work to address inequities, complementing the efforts of "Healthier Together" in this regard.

It will help to address the huge gap observed between clinical trial outcomes and real-life outcomes for patients with CVD and facilitate a drive towards real world evidence (RWE) generation.

This Action will be a **critical accelerator** for all pillars of a CVH plan, and the "Healthier Together" initiative.

A European Cardiovascular Health Observatory

EACH proposes the establishment of a European Cardiovascular Health Observatory to capture important developments across the spectrum of cardiovascular health in Europe, highlighting beacons of excellence, good practices, and specific methodology on how these could be replicated and scaled, and integrated into member states' national CVH action plans. This action responds to a universal concern that much is happening in isolation, there is duplication and wasted opportunity to 'leapfrog', and 'key enablers' are needed for good practices to be implemented and adopted elsewhere. The Observatory would enlarge and deepen the work undertaken in the framework of "Healthier Together" on good practice exchange. Structured collaboration should also take place with the European Centre for Disease Control. The Observatory should also oversee a process whereby member state experts can provide peer review input on others' national CVH Action Plans. Analogous to the EU Semester process, such a role for the Observatory will allow the largest expert input into the elaboration and refinement of national CVH Action Plans and health systems' readiness in this regard.

A 'hub and spoke' methodology and approach of the European Reference Networks in Rare Diseases should be explored in establishing this Observatory, including rare CVDs. Synergies at global level should be found with current data observation activities.

The Co-Creation of National CVH Action Plans

There should be co-creation of national CVH action plans by government, regional authorities and CVH stakeholders in every Member State, drawing on the model in Spain, currently the only country in Europe with a dedicated plan. Each national CVH action plan will reflect the national context and culture and provide an essential springboard for national implementation of a European CVH Plan with appropriate emphasis, investment and targets on primary, secondary and tertiary prevention. The plans should complement existing national plans (stroke, kidney etc) where these exist. Without deliberate commitment to act at national level, our vision for CVH in Europe will falter. Each pillar of the European CVH Plan, as it evolves, should therefore

include a specific section on how this will be implemented in a national context and related performance indicators.

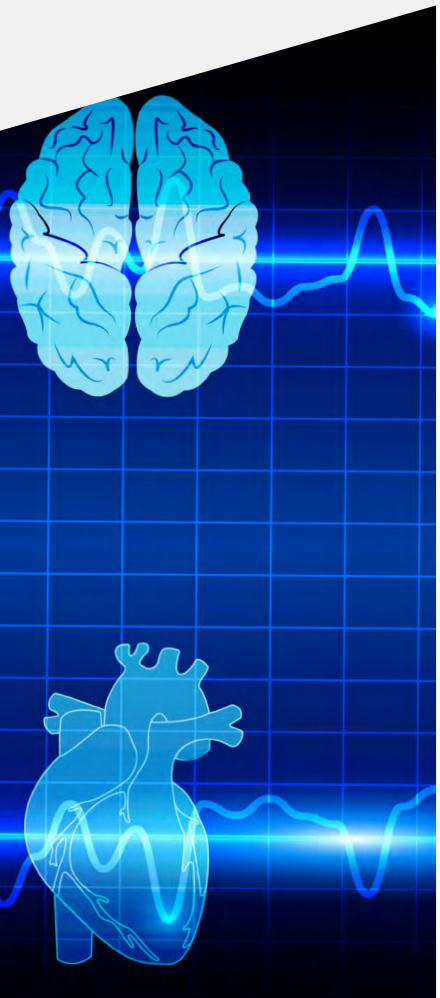
Creating an incubator and progressive policy environment for digital transformation in CVH

Much is happening in this fast-moving area, and this action will help to create a progressive policy environment and facilitate innovation, trust and uptake of digital health solutions across the CVH community across Europe and minimise the digital divide in Europe.

EACH envisions the spearheading of digital transformation in cardiovascular health through user-led needs assessments and gap analyses, co-development of relevant digital tools and resources, digital health literacy programmes, drawing on EU level instruments and project results in the area of digital health, and creating a European Compact on the regulatory environment, incentives, and value-based reimbursement of digital health solutions for CVH, with roll out at national level.

Summary of horizontal, cross-cutting actions

1. A European CVH Knowledge Centre
2. A European Cardiovascular Health Observatory
3. The Co-Creation of National CVH Action Plans
4. Creating an incubator and progressive policy environment for digital transformation in CVH



VERTICAL ACTIONS

Primary prevention[30] to decrease premature mortality and morbidity at population level

Many people are already disabled by ill-health before they reach retirement age. Greater reduction in exposure to the main behavioural risk factors – tobacco, unhealthy diet, physical inactivity, and harmful use of alcohol would increase the number of healthy life years. Effective population-wide interventions to prevent CVD have the potential to provide both human and economic benefit with considerable return on investment but are not currently exploited[31] Efforts to ensure that people both adopt and adhere to such interventions are also important to ensure strong impact of these actions.

Close collaboration will take place with the "Healthier Together" Initiative and the Beating Cancer Plan and its key stakeholders to identify the most effective policies and measures to reach out and manage individuals at high risk of developing CVD and pilot these specifically as part of the CVH National Action Plans, in countries where explicit policies and programmes are currently absent. Based on these pilots, dedicated programmes will be developed with direct involvement of the target groups themselves.

Secondary prevention through screening for early detection and precision diagnosis - A European Cardiovascular Health Check

A life course approach must be adopted for screening for metabolic and inherited risk-factors, detection, and precision diagnosis, at birth, throughout childhood and specific junctures in adulthood and later life, under the umbrella action of the "European Cardiovascular Health Check" and incorporated into member states' national CVH action plans. This would include a strong health literacy, behavioural component, including, where needed, genetic counselling, and herald a shift towards 'personalised prevention'.

This will apply to emerging diagnostics and data-driven health technology, as they hold the promise to move care from a point-in-time, intervention-only focus to a more holistic "whole patient" view by improving the accuracy of diagnosis, appropriate interventions as required, and evidence-based post-procedural care.

To achieve this ambitious action, current gaps will be addressed, through developing guidelines / consensus by medical societies and health authorities on whom should be screened, and when; and awareness raising campaigns targeted at health care professionals and the wider public.

This Action will also create a framework for early detection through training programmes on regular screening and precision diagnosis, to train healthcare professionals, especially within primary care and specialist nursing settings and lead to a better understanding of risk factors to practice intervention in early screening detection and diagnosis.

Early intervention, access to care and optimal treatment

A European network should be created to encompass recognised comprehensive CVH centres in every Member State, facilitating the uptake of diagnosis and treatment, as well as rehabilitation and long-term care and effective management, including adherence to medicines and medical advice.

This network would build on and complement existing efforts, for example, in the area of accredited stroke units. Such cross-border collaboration, drawing on the experience of the European Reference Networks, will improve patients' access to a personalised care pathway and management according to the latest clinical guidelines, including access to innovative treatments and technologies. Medication non-adherence harms health and increases healthcare costs. Poor adherence is estimated to contribute to nearly 200 000 premature deaths in Europe per year, and as such a focus on adherence to medical direction is an important opportunity to improve health outcomes and the preventive possibilities with early intervention, particularly in cardiovascular disease as a chronic health condition[32].

Emphasis will be placed on shifting the burden of hospital care as appropriate and focus on primary care/ community care and home care, and self-management, supported by digital health solutions. A specific role of this Network will be to monitor the return on investment of prescribed therapies and other

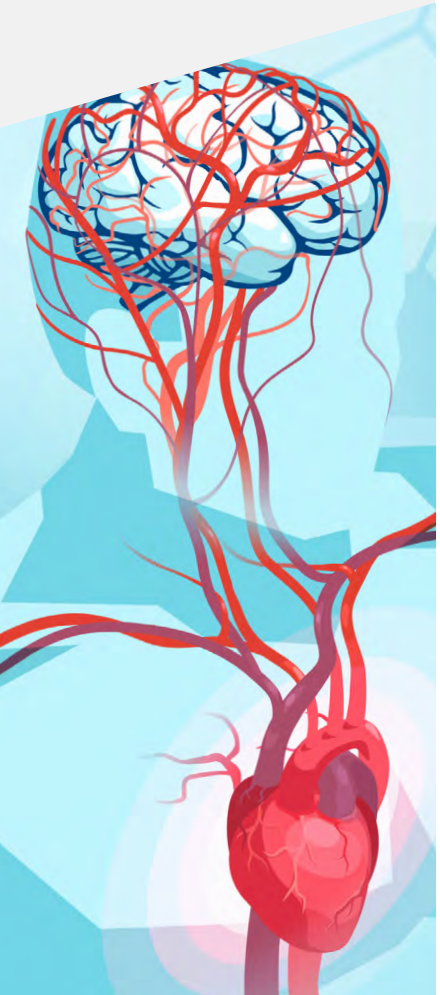
innovations, and to make recommendations on opportunities to improve adherence to medical orders, particularly with respect to preventive medications and appropriate health behaviours, including risk awareness.

A second critical action will focus on gaps in CV health in the workforce across Europe, with a strategy to create incentives for CV healthcare professionals across the spectrum of care. A major component will focus on professional and continuous professional development needs for optimum and personalised cardiovascular health and support in a fast-changing environment. Particular emphasis will be placed on patient empowerment, psycho-social support and shared decision-making. This action will also reflect the importance of structured, specialist multidisciplinary teams for those at highest CVD risk.

A dedicated large-scale study will be undertaken to explore person-centred, value-based healthcare through the lens of cardiovascular health, and specific impacts in terms of patient outcomes. This will also examine the effective and consistent implementation of guidelines, the role of integrated care units, and structural weaknesses in health systems and how they can be addressed most effectively to improve the care pathway for those affected by CVD.

Rehabilitation

Across the European Union, millions of patients live with the aftereffects of heart attacks and strokes. A crucial part of the treatment is rehabilitation including counselling, medical treatment and psychological support. Cardiac and stroke rehabilitation programmes help prevent recurrence, improve functional capacity, recovery and psychological well-being. They allow patients to get back to normal, and with an optimal quality of life[33]. Rehabilitation is essential in enabling people with functional limitations to actively remain/return/participate in their life, work, and education.



Rehabilitation includes occupational, physical, speech and language therapy, with input from psychologists and social workers as necessary. It should involve a multidisciplinary approach and a clear plan for discharge from hospital with documented responsibility for continuing rehabilitation needs in the community.

Access to rehabilitation varies greatly across Europe[34].

This action would adopt a European definition of cardiac and stroke rehabilitation, and support the implementation of good practice in rehabilitation as proposed, for example in the Stroke Action Plan for Europe[35]. This is framed around the UN Convention on the Rights of People with Disabilities (UNCPDR) and the right to stroke rehabilitation. The action would establish a network of experts from across the EU to identify barriers and opportunities for the uptake of cardiac and stoke rehabilitation, building on the Stroke Action Plan for Europe, exploring also digital health solutions.

Quality of life and other psychosocial outcomes across the spectrum of cardiovascular diseases

There is considerable evidence that psychosocial factors contribute to the etiology and the prognosis of cardiac illness[36]. Some of these factors in-

clude low socio-economic status, lack of social support, stress at work and in family life, hostility, depression, anxiety.

Anxiety, depression, and stress are among the most important psychological risk factors related to heart disease and are predictive of mortality and/or of a worsening of the quality of life. Psychosocial risk factors are also linked to treatment adherence, type of lifestyle and the promotion of health in patients and populations. It is also important to consider the positive effects of good family and social support on the outcome of CVD in terms of better adherence and the decrease in new hospital admissions.

Quality of life relates to the many psychosocial outcomes which are impacted following a CVD event. Those living with or recovering from a CV condition require access to ongoing CV health maintenance, structured programmes, peer to peer, psychological and community-based support (nursing and care, medical adherence programmes, remote monitoring).

The ultimate goal for all stakeholders should be improving patient experiences, outcomes, and value throughout the care continuum. It is widely acknowledged that new technology could play a major role in improving quality of life.

Patient organisations play a key role are instrumental in responding to patient/user/carers needs after a CV event and should become a formal part of a support network and resourced accordingly.

This action would create a standardised instrument measuring quality of life and other PROMS related to it, of people living with CVD and their families across the Member States, to contribute to a greater understanding and awareness of CV Health and quality of life in Europe and where additional investment is needed. Indicators would be based on a large-scale CVD patient study (PROMs and interviews with patients) on how CVD affects patients and their families, how their quality of life could be improved and how the impact of CVD on their daily lives could be minimised.

Life after a CVD event must be included in each national CVD plan to address survivors' and their families' long-term unmet needs and minimum standards set for what every CV survivor should receive regardless of where they live. Both physical and mental health must be addressed through a common set of guidelines, that specifically addresses longer term CV health management, including physical and mental health. To achieve this, a common set of guidelines are needed that specifically address longer term CV health management.

Summary of Vertical Actions

1. Primary Prevention to decrease premature mortality and morbidity at population level
2. Secondary prevention through early detection, screening, and diagnosis
3. Early intervention, access to care and optimal treatment
4. Rehabilitation
5. Quality of life and other psychosocial outcomes across the spectrum of cardiovascular conditions

A CVH MISSION: COMPRISING A NEW RESEARCH AND INNOVATION AGENDA, IN THE FRAMEWORK OF HORIZON EUROPE

EU Missions are a new approach to bring concrete solutions to some of the greatest challenges facing Europe today. They have ambitious goals to deliver concrete results by 2030. They deliver impact by putting research and innovation into a new role, combined with new forms of governance and collaboration, as well as by engaging citizens. EACH proposes a European CVH Mission to support and inform the CVH Plan, mirroring the current Cancer Mission and the Beating Cancer Plan at European level. This is also called for by a recent EESC opinion[37].

Strategic research efforts in the field of CVD at EU level through a CVH Mission should address fragmentation, exploit and expand existing research capacity and bring investment to respond to unmet needs.

Investments in basic and translational CVH research

Investment in research is the foundation for progress in CV medicine. Innovative research tools allow us not only to decipher disease causes and pathways, but also to track the trajectory of diseased cells and the impact of individual environment and comorbidity on disease progression. Molecular investigations in cell regeneration and gene therapies are re-emerging, offering highly specific treatment options for even rare CVD. While we see these exciting achievements in research, the translation of these new findings into useful technologies and their ultimate implementation into clinical care is inadequate and insufficient. A fundamental element to effectively addressing cardiovascular disease is more financial investment in basic and translational CV research.

The EU is enabling the formation of trans-national research consortia by bringing together the most renowned scientists from all Member States to pool their experience and capacity on the greatest challenges in research, development, application and transformation of clinical care and to address unresolved issues such as improved precision of CV medicine, causal therapies, regenerative therapies, high-resolution molecular and clinical phenotyping, to name a few.

An enabling environment for pragmatic and well randomised conducted trials

Well-conducted randomised clinical trials are the bedrock of safe and effective, evidence-based treatment of CVD. However, the cost and complexity of clinical trials in cardiovascular disease have increased disproportionately. This means that many potential new treatments are abandoned before their efficacy has been thoroughly evaluated[38]. A dedicated CVH Mission would help to address this through learnings from other disease areas and pre-compe-

titive collaboration. It can therefore facilitate the creation of an enabling environment for CV Clinical Trials and deeper collaboration across the CVH multistakeholder community.

A dedicated CVH research and innovation agenda

A CVH Mission would drive a dedicated CVH research and innovation agenda that could include:

- Precision diagnosis through high resolution medical imaging using AI and digital tools.
- Precision medicines in addressing cardiovascular diseases, building on the advances in molecular, genetic, analytical, and therapeutic tools
- Enhancing our understanding of the causes and best care of rare cardiovascular diseases.
- Investigating the interaction between CVD and other non-communicable and communicable diseases
- Personalised approaches to CVH, by using big data/machine learning throughout the disease journey from primary prevention to rehabilitation, chronic - and after- care with a focus on the goals and outcomes that matter to people and patients
- Predictive technology for the early identification and intervention in ASCVD, which currently accounts for over 80% of heart attacks
- Leveraging AI to better understand the fundamental biological processes and physiology for CVH
- Invest in research and translation of methods to repair of the heart and blood vessels
- Further improvement of treatment options of chronic heart failure and atrial fibrillation
- Optimising palliative and end of life care for patients with CVD /and comorbidities
- Addressing cardiovascular healthcare costs through better management/ Return on Investment studies in better/ earlier access to treatments/ Value Based Health Care
- Digital twins
- Patient and population education and empowerment
- Modelling management of CVD in integrated pathways, through heart centres.

The CVH Mission would encourage more structured collaboration between academia, CROs, patients, regulators, and industry to modernise the International Council of Harmonisation Good Clinical Practice Guidelines, through a dedicated funding programme. It would also explore EU methodology for Early Feasibility Studies in accordance with the Medical Devices Regulation to improve patient access in CVH.

Translational research capacity through the biotech sector should be enhanced, though, for example, incentivising SME development.

The CVH Mission would place major emphasis on the translation of research outcomes and evidence into CVH policy and implementation at national level to support health system transformation, and new models of care. This could be enhanced by fully integrated multistakeholder research partnerships.

IMPORTANT DIMENSIONS OF THE ARCHITECTURE OF A EUROPEAN CVH PLAN

The success and impact of a European CVH Plan will be shaped not only by what is achieved over the next few years, but also by how it is achieved, leaving no-one and no country behind. The Plan must address societal barriers, underserved populations, discrimination on all grounds, and fundamental inequalities pervading health systems across Europe.

EACH sees the following areas as critical in building an inclusive, effective Plan.

A LIFE COURSE APPROACH

Recognising that CVD has many facets, is highly complex, and can be inherited, acquired and and/ or acute, it is crucial that a life course approach[39] is inherent to the European CVH plan, covering all age groups. There are many rare CVDs that affect a large population of EU children and young adults, impacting hugely quality of life and CVD mortality[40]. At 60 +, or the so-called 'third age', many age-related conditions can be detected (hypertension, structural heart diseases, atrial fibrillation, heart failure etc) and early intervention can have a great impact. Appropriate emphasis should also be placed on family-based care, to support and empower people affected by CVD or risk factors, and family members appropriately, regardless of their age.

INCLUSIVE GOVERNANCE

Including CVH stakeholders as equal, active partners in delivering a CVH plan and amplifying its success is fundamental.

A dedicated multi-stakeholder advisory board should be established to guide and monitor the CVH Plan, including a representative from the CVH community from every member state, and EACH partners at European level. Representation should also be sought from the citizen juries which helped to draft the CVH plan.

A representative from the sectors EACH represents (scientific societies, health care professionals' bodies, patient organisations, health industry, health insurance and public health organisations) should sit on any implementation board of the CVH Plan.

Diverse CVH stakeholders should be involved meaningfully in relevant Joint Actions, projects and research to implement the CVH Plan and Mission and be appropriately resourced for this involvement. Calls for Proposals should reflect this explicitly.

A patient and public engagement panel should be created to support the implementation of the CVH Plan and its monitoring and evaluation and to ensure the highest standards of patient and public engagement and meaningful involvement of patients' and citizens' organisations characterise all aspects of the Plan.

OTHER RELEVANT EU INSTRUMENTS AND WIDER AGENDAS

A European CVH Plan, whilst singular in its vision and goals, cannot be undertaken in isolation. The wider socio-political context described earlier in this Plan is key, and the Plan should relate and contribute, where appropriate and relevant, to other major EU Actions and Initiatives, such as the Semester Process, helping to address health related country specific recommendations, work undertaken in DG Reform, the Recovery and Resilience Facility to build back better post-Covid, the other EU Missions on Cancer, SMART cities, and action on climate change.

AGILE, INNOVATIVE PARTNERSHIPS AND FUNDING: DOING THINGS DIFFERENTLY

For a European CVH plan of this magnitude to achieve its ambitious vision, we must be courageous in doing things differently. There is now a real appetite at European level to advance innovation in all its guises: therapeutic, technological, digital, systems and social innovation, but if we approach this in a traditional conservative way, without embedding innovation in how we work together to ensure the momentous impact that is needed, we will fail. The new Innovative Health Initiative is providing fertile ground for this, but true multi-stakeholder/ Public Private Partnerships and shared leadership must underpin other programmes and structures to address the burden of CVD, overcome treatment bottlenecks, and positively influence population health. Patient and public engagement is also intrinsic to this shift.

Arguably, funding is no longer the biggest challenge to addressing CVH at European and national level, however it is crucial to channel this funding appropriately towards improving CVH for all. There are numerous funding sources through EU4Health, Horizon Europe and the Innovative Health Initiative, Digital Europe, the Cohesion Fund, the Recovery and Resilience Facility, amongst others. Coordination and optimisation across and within these programmes remain problematic, and there should be a consolidated "one stop shop" for CVH stakeholders interested in contributing to implementing the Plan, to understand prospective partnership opportunities and timelines and how these contribute to the overall vision of the Plan.

A longer-term perspective is also needed towards CVH funding to fuel a move from a 'point-in-time' intervention towards a more personalised patient care pathway.

INTERINSTITUTIONAL COLLABORATION AND THE WIDER EUROPE

The geographic remit of the CVH Plan is the European Union. Strong collaboration should take place with WHO-EUROPE, to create synergies with its work on CVH, and to ensure that the CVH plan and outputs provide valuable impetus and resources in EU neighbouring countries, including the UK, and conversely the CVH Plan is informed and strengthened by important advances in these countries.

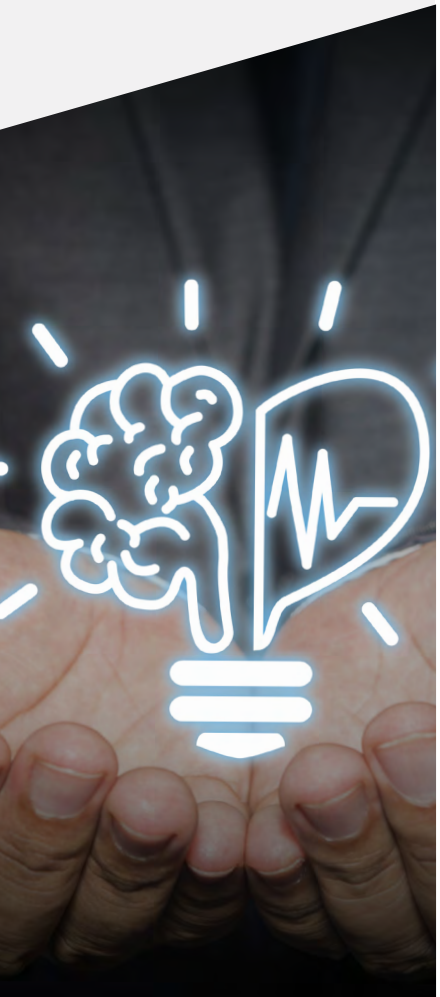
The Plan will also draw on relevant initiatives by OECD[41] on NCDs and CVH specifically.

As the Plan progresses, a dedicated chapter should be included in "The State of Health in the EU" led by the European Commission and supported by OECD and the Observatory on Health Systems and Policies. Appropriate indicators should also be included within EUROSTAT.

THE GLOBAL DIMENSION

The European CVH Plan and its implementation should be informed by emerging research and good practice from other regions of the world through relevant global agencies and international organisations such as the World Heart Federation.

The European CVH plan should aspire to be "first in class" across the globe, and an inspiring and powerful regional example of a holistic, robust, deliberate gamechanger in saving and improving lives.



CONCLUSIONS

EACH partners agreed this proposal for a dedicated European Cardiovascular Health Plan and CVH Mission and a strategy for EACH, at the end of April 2022. All EACH partners are committed to working together to deliver on this ambition, and to support the European Union in playing its vital role in addressing the biggest health burden facing its people. We firmly believe in our vision – to reduce mortality due to CVD by 30% by 2030, to give every person living in the EU a Cardiovascular Health Check, and CVD patients' access to quality CV care that meets their needs and goals. This is not only achievable, but critical for the future of Europe, with major implications for the sustainability and resilience of health systems in every country, and transformative for Europe's people and patients. We look forward to ongoing dialogue with the EU Institutions to shape the further development and refinement of the proposals included in this document, building on, and learning from the "Healthier Together" initiative.

ANNEX 1 : THE METHODOLOGY TO DEVELOP THE EUROPEAN CVH PLAN

The approach comprised four core elements: desk research; interviews with EACH Partners; drafting of the EACH Action Plan; and consultation / refinement.

The desk research was focussed on existing material produced by EACH (Joint Statement and Proposal for an EU4Health Joint Action), relevant EU/ OECD / WHO policy materials, and the most important key strategic documents shared by EACH Partners.

A 1:1 interview took place with all EACH partners, to gather insights to inform the first draft of this document.

A first draft was circulated with a template for EACH Partners to submit comments and reflections on the EACH Action Plan.

A second iteration integrated comments and was circulated to all EACH Partners for final comments in advance of a Consultative Workshop on 25th April which addressed outstanding strategic / policy questions.

A final draft was approved by EACH Partners at the end of April.

ANNEX 2 : ABOUT EACH AND A LIST OF EACH PARTNERS

The European Alliance for Cardiovascular Health (EACH) brings together leading European and international organisations around joint activities to promote cardiovascular health as a policy priority at EU level.

Launched on 27 September 2021, the Alliance partners cover all aspects of cardiovascular care: from the patients who suffer from the disease to the clinicians and health professionals who take care of them, from health insurers to research organisations, and industries that develop the medical and technological innovations to improve the management and care of CVD. EACH provides a platform to aggregate knowledge and expertise of key stakeholders active in the field of cardiovascular health, and to advise and

guide policymakers. The Alliance calls for greater focus on improving cardiovascular health and reducing the burden of cardiovascular disease at the European level.

1. International Association of Mutual Benefit Societies (AIM)
2. European Trade Association representing the medical ima ging, radiotherapy, health ICT and electromedical industries (COCIR)
3. European Atherosclerosis Society (EAS)
4. European Chronic Disease Alliance (ECDA)
5. European Congenital Heart Disease Organisation (ECHDO)
6. European Federation of Pharmaceutical Industries Associations (EFPIA)
7. European Heart Network (EHN)
8. European Kidney Health Alliance (EKHA)
9. European Society of Cardiology (ESC)
10. European Stroke Organisation (ESO)
11. European Society of Vascular Surgery (ESVS)
12. European Confederation of Pharmaceuticals Entrepreneurs (EUCOPE)
13. The European FH Patient Network (FH Europe)
14. Global Heart Hub (GHH)
15. MedTech Europe (MTE)
16. Stroke Alliance for Europe (SAFE)
17. World Heart Federation (WHF)

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