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Vaccines Europe

EU Cardiovascular Health Plan

EFPIA & Vaccines Europe position paper

September 2025

Introduction

With more than 13 million new cases diagnosed annually[1] and costs amounting to €282 billion[2] each year, the burden of Cardiovascular Disease (CVD)[3] on patients, healthcare systems, and society at large is staggering. One in three deaths in the EU are due to CVD, 20% of all premature deaths (before the age of 65) are caused by cardiovascular conditions, making it the number one killer in Europe.

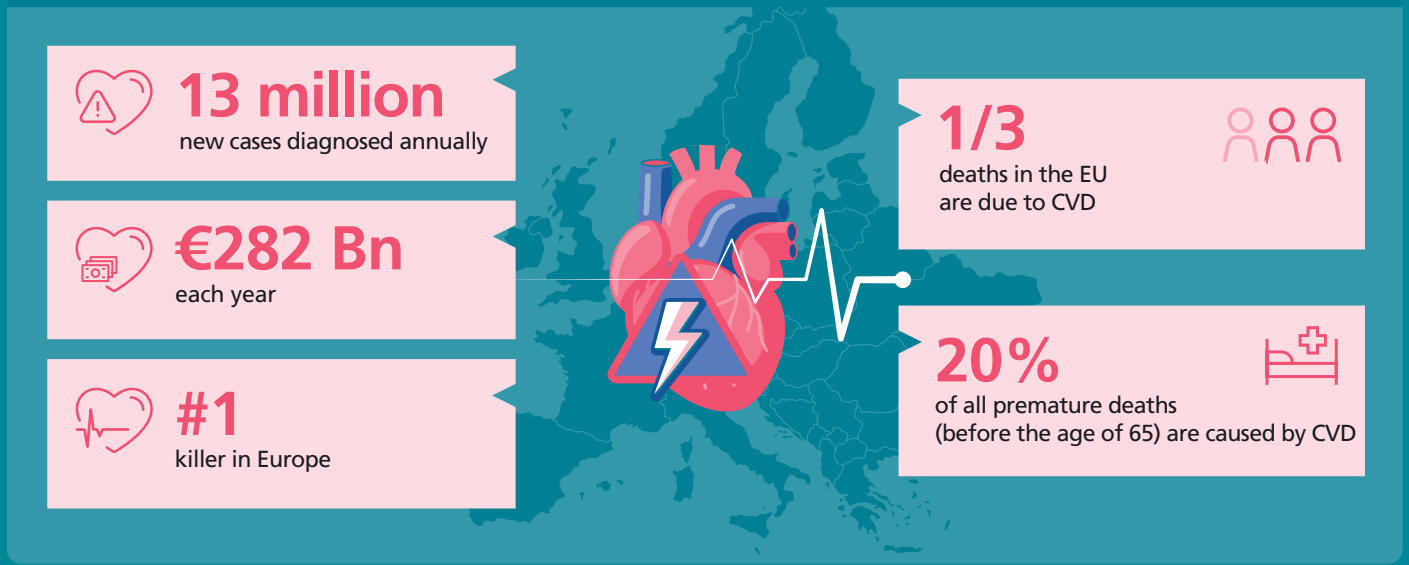
To effectively address this pressing public health issue, robust action on improving cardiovascular health is needed at all levels, that not only focuses on reducing premature and preventable deaths, but also fosters innovation, equity, and resilience in healthcare. Prevention, early detection, timely intervention and long term, person-centred management, are essential for improving health outcomes and quality of life for patients, as well as continued research and development to address unmet health needs.

EFPIA and Vaccines Europe welcomes the forthcoming EU Cardiovascular Health (CVH) Plan which will deliver much-needed political momentum for a renewed and coordinated effort to improve cardiovascular health in Europe. The plan should set out impactful, high-level targets and actions focused on reducing premature mortality and morbidity with clear added value which can be developed and implemented with all stakeholders, including patients, healthcare professionals and industry.

The pharmaceutical industry has greatly contributed to the improvement of healthcare and health outcomes during the last number of decades, including for people living with cardiovascular disease. The life sciences sector brings extensive experience in translating scientific discovery into tangible health solutions that benefit patients and society - leveraging this expertise represents an asset and will be vital for building resilient health systems capable of addressing current and future cardiovascular challenges.

1 European Society of Cardiology (2020) Fighting cardiovascular disease – a blueprint for EU action
2 Luengo-Fernandez et al., (2023), Economic burden of cardiovascular diseases in the European Union: a population-based cost study. https://academic.oup.com/eurheartj/article/44/45/4752/7251239
3 Cardiovascular disease (CVD) is a group of conditions affecting the heart or blood vessel - they include heart attacks and strokes, as well as arrhythmias and congenital heart disease. It remains the leading cause of death across Europe, one in every three deaths are caused by CVD.

The burden of CVD in the EU



Scope and ambition of an EU Cardiovascular Health Plan

EFPIA and Vaccines Europe supports a **robust** and **well-resourced** EU CVH Plan as complement to a horizontal approach to tackling Non-Communicable Diseases (NCDs). The EU CVH Plan should set out actions with **clear added value** which can complement and create synergies between Member State national policies, and include clear objectives and **measurable targets**, for example by aiming for the reduction of CVD premature and preventable death by one third by 2030, in alignment with the UN Sustainable Development Goal 3.4. [4]

The plan should embrace a comprehensive approach to primary, secondary and tertiary prevention, care and rehabilitation. The primary objective should be to **push back the morbidity curve** by focusing on **early detection** years before the clinical manifestation of disease. This can be achieved by taking an evidence-based, people-centred and **proactive approach to prevention** of cardiovascular disease, aligning with the latest scientific advances and clinical guidelines and taking into account major modifiable risk factors, including LDL-C, hypertension, atrial fibrillation and also conditions such as chronic kidney disease, thyroid disorders, obesity and diabetes - diseases which significantly contribute to the course and prognosis of CVD, but remain sub-optimally managed.

Learning from the successes of the Europe's Beating Cancer Plan, the EU CVH Plan should at its heart place **reduction of disparities** in access to prevention, diagnosis and treatment, and health outcomes, across different population groups with particular attention to removing inequities based on gender, socioeconomic factors and place of living.[5] Achieving equitable access that improves outcomes for all population groups, should guide the spirit of the EU CVH Plan.

Furthermore, the plan should support continued **research and innovation** to further improve health outcomes across CVDs and cater to unmet health needs, while also contributing to a vital European research eco-system and competitiveness.

The design and implementation of the EU CVH Plan should build on **experiences and good practice** from the Europe's Beating Cancer Plan - including the need for a goal-driven and whole-disease continuum approach - and be executed in **collaboration with all stakeholders** including patients, healthcare professionals, scientific societies and industry. It should encompass strategies that would address workforce shortfalls to ensure that implementation of the plan is feasible at the provider level. The plan should also aim to **scale up already existing initiatives** co-funded by the EU, including relevant projects developed through the Innovative Medicines Initiative and Innovative Health Initiative.[6]

4 See the EACH Roadmap https://www.cardiovascular-alliance.eu/wp-content/uploads/2025/04/EACH-A-EUROPEAN-CARDIOVASCULAR-HEALTH-PLAN-THE-ROADMAP_FINAL_WEB.pdf
5 Schultz WM, Kelli HM, Lisko JC, Varghese T, (et al.) (2018) Socioeconomic Status and Cardiovascular Outcomes: Challenges and Interventions. Circulation. 2018 May 15;137(20):2166-2178
6 Cities@Heart; EuroHeartPath, CarePath, COMBINE-CT iCARE4CVD UMBRELLA GRACE CARDIATEAM

The implementation of a comprehensive EU CVH Plan that would deliver tangible results to people's health and wellbeing needs to be supported through **resources necessary** in order to deliver true value for Europeans. The EU CVH Plan therefore needs to be supported through **robust funding** e.g. through the current EU4Health programme and Horizon Europe, and the next Multi-Annual Financial Framework.

FLAGSHIP INITIATIVE
Implementation of Cardiovascular Health Checks

The EU should adopt a Council recommendation to Member States on introducing Cardiovascular Health Checks in primary care and support their implementation. The Health Checks should include screening for a comprehensive range of cardiometabolic risk factors, to enable prevention and early detection of cardiovascular disease as well as obesity and diabetes which are both major modifiable risk factors for CVDs.

These health checks should be automatically and opportunistically included whenever routine bloodwork is ordered in primary care for adults and be performed regularly for individuals from an age set out in the plan (e.g. the age of 40), and for adults (age 18+) who are in high-risk groups (e.g. family history of premature CVD, people with familial hypercholesterolemia, obesity, diabetes and chronic kidney disease). These health checks should increase in frequency for people at risk for developing CVD.

1 Scaling up of strategies for prevention and early detection, in particular through:

- **EU Council Recommendation** supporting alignment of Member States to ensure efficient implementation of the health checks at national level, with particular focus on establishment of common European targets applicable across Member States e.g. targets for the percentage of the population that underwent a CV health check by 2030 and 2035 respectively.
- Support of **the implementation of the Cardiovascular Health Checks in Member States**, in particular through education of healthcare professionals in primary care and the implementation of evidence-based protocols, including the age-related guidelines developed by the relevant professional societies (e.g. European Society of Cardiology and the European Atherosclerosis Society) that will ensure preventive action if required.
- Enhancement of **immunisation programmes** to improve vaccine coverage rates and prevent cardiovascular complications in at-risk populations.

2 Improve management and care for people living with cardiovascular disease, in particular through:

- Development of a **European network of integrated CVH centres of excellence** across the EU Member States to optimise clinical practice of cardiometabolic conditions across Member States.
- Supporting Members States to implement **treatment adherence** programs and drive focus on reaching treatment goals.
- Creating an **EU Inequalities Registry for CVD patients**, implemented by the Joint Research Centre, to generate data on the impact of CVD on underserved populations and to bring together existing cardiovascular registries in Europe.

3 Foster innovation and the clinical trial eco-system, in particular through:

- Establishment of a dedicated **CVH Research Mission** and ensuring financial investment in basic and translational CV research.
- Enabling the European network of **CVH centres of excellence** to support optimisation of clinical development through multi-stakeholder collaboration and public-private partnerships.

4 Utilisation of data and digital health solutions, in particular through:

- **Scaling up the existing successful pilots and initiatives** in the framework of IMI/IHI to enhance the use of digital health applications, specifically targeting digital solutions that may bridge gaps in workforce shortfalls for health checks.
- Establish a **cardiovascular health pilot within the European Health Data Space.**

1 Investment in prevention and early detection

Many of the CVD related deaths and poor quality of life could be avoided by adequate investment into prevention and early detection. By making prevention a cornerstone of cardiovascular health, addressing the root causes of heart diseases before they manifest into serious conditions, one can improve outcomes across populations and also ease the considerable economic burden on healthcare systems and societies.

In order to fully tackle the burden of cardiovascular disease in Europe, health systems need to pivot to a more proactive approach to prevention and preventive care, early detection and management of risk factors through appropriate interventions, including therapeutics and immunisation, informed by the Cardiovascular Health Checks. Ultimately, preventing the onset and progression of cardiovascular disease can only be fully achieved through citizen's awareness of their health status and ability to access the appropriate healthcare interventions without delay.

Primary prevention

Primary prevention aims to stop the disease progression before it starts by identifying and addressing existing risk factors like elevated LDL- cholesterol, as well as inherited lipid disorders (familial hypercholesterolemia and elevated levels of Lp(a)), hypertension, obesity, and smoking. Strategies should include not only promoting healthy behaviours but also immunisation which can play an important role in cardiovascular health by reducing the incidence of infectious diseases that can precipitate or exacerbate cardiovascular events.

Immunisation can reduce the incidence of infectious diseases such as influenza, pneumococcal infections, COVID-19, RSV (Respiratory Syncytial Virus) and herpes zoster, and have been shown to

lower the risk of myocardial infarction, stroke, and heart failure by mitigating systemic inflammation and preventing infections that strain the cardiovascular system. **People are 6 times more likely to suffer a heart attack if diagnosed with influenza, even when they don't have previously diagnosed CVD, and vaccination against flu can reduce CVD related deaths with 33%.**[7] In individuals with existing heart conditions, a recent ESC clinical consensus document highlights the importance of immunisation as a preventive strategy that improves survival, reduces hospitalisations, and enhances quality of life.[8]

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Preventing infectious diseases particularly respiratory infections through life course immunisation is an easy and cost-effective means to prevent not only the burden of disease from the infections targeted, but also the possible repercussions on the cardiovascular system. [9] [10] [11] [12] [13] [14]

Secondary prevention – screening, early diagnosis and timely intervention

The incidence of CVD in Europe remains high, even though premature CVD onset could often be prevented or postponed with appropriate preventative and treatment interventions. While programs to encourage healthy lifestyles and raise awareness of the link between diet, physical activity and CVD should be further strengthened, a primary prevention approach alone does not provide a solution for people already at high risk, living with comorbidities sharing close links to CVD, or having a genetic predisposition.

Early detection followed by timely and effective treatment is critical to reducing the risk of cardiovascular complications, comorbidities and death. A significant percentage of CVD deaths can be attributed to known risk factors, both modifiable (for example, high LDL cholesterol, high blood glucose, hypertension and atrial fibrillation) and inherited (such as Lipoprotein(a) and familial hypercholesterolemia and cardiomyopathies).

Some of these modifiable risk factors are linked to comorbid diseases such as obesity, kidney diseases, thyroid disorders and diabetes and can therefore be reduced by timely management of these diseases according to clinical guidelines.

- People with type 2 diabetes are two to four times more likely to develop CVD than those without diabetes[15]. In Europe an estimated 61 million adult live with diabetes[16], meaning over 30 million people are likely to develop cardiovascular complications. People with diabetes tend to develop CVD at younger age and with more severe outcomes, often reducing their capacity for a fully productive life. Over 70% of adults with type 2 diabetes, also have hypertension, high cholesterol, chronic kidney disease or obesity, compounding their cardiovascular risk.[17]
- Obesity is still inadequately addressed compared to other CVD risk factors despite its link to a wide range of cardiovascular disease manifestations, such as atherosclerotic disease, heart failure, thromboembolic disease, arrhythmias, and sudden cardiac death. Around 67.5% of deaths related to high BMI are attributable to cardiovascular disease. Obesity is responsible for approximately 23% of treatment costs for cardiovascular disease.

7 Jeffrey C. Kwong, M.D., Kevin L. Schwartz et al (2018) Acute Myocardial Infarction after Laboratory-Confirmed Influenza Infection New England Journal of Medicine, Vol 376(4): 345-353

8 Bettina Heidecker, Peter Libby, Vassilios S Vassiliou, (et al), Vaccination as a new form of cardiovascular prevention: a European Society of Cardiology clinical consensus statement: With the contribution of the European Association of Preventive Cardiology (EAPC), the Association for Acute CardioVascular Care (ACVC), and the Heart Failure Association (HFA) of the ESC, European Heart Journal, 2025;, ehaf384, https://doi.org/10.1093/eurheartj/ehaf384

9 Modin, D., Lassen M. C. H., Claggett, B., et al (2023) Influenza vaccination and cardiovascular events in patients with ischaemic heart disease and heart failure: A meta-analysis. Eur J Heart Fail., 25(9), 1685-1692. https://doi.org/10.1002/ejhf.2945. Epub 2023 Jul 5.

10 Udell JA, Zawi R, Bhatt DL, et al. (2013) Association Between Influenza Vaccination and Cardiovascular Outcomes in High-Risk Patients: A Meta-analysis. JAMA. 2013;310(16):1711–1720. https://doi.org/10.1001/jama.2013.279206

11 Vlachopoulos CV, Terentes-Printzios DG, Aznaouridis KA, Pietri PG, Stefanadis CI.(2014) Association between pneumococcal vaccination and cardiovascular outcomes: a systematic review and meta-analysis of cohort studies. Eur J Prev Cardiol. 2015 Sep;22(9):1185-99. doi: 10.1177/2047487314549512. Epub 2014 Sep 24. PMID: 25252595.

12 Shi, T., Vennard, S., Jasiewicz, F., Brogden, R., Nair, H.; RESCEU Investigators. (2022) Disease Burden Estimates of Respiratory Syncytial Virus related Acute Respiratory Infections in Adults With Comorbidity: A Systematic Review and Meta-Analysis. J Infect Dis., 226(Suppl 1): S17-S21. doi: 10.1093/infdis/jiab040.

13 Xie, Y., Xu, E., Bowe, B. et al (2022). Long-term cardiovascular outcomes of COVID-19. Nat Med 28, 583–590 https://doi.org/10.1038/s41591-022-01689-3

14 Office of Health Economics (OHE). Adult vaccination: A smart investment for the EU. Office of Health Economics, 2023. Available at: https://www.ohe.org/publications/adult-vaccination-a-smart-investment-for-the-eu/

15 European Society of Cardiology (2023);Clinical Practice Guidelines CVD and Diabetes https://www.escardio.org/Guidelines/Clinical-Practice-Guidelines/CVD-and-Diabetes-Guidelines

16 IDF Diabetes Atlas, 2023

17 European Society of Cardiology & European Association for the Study of Diabetes (EASD). Joint Recommendations

- Targeting systemic inflammation has the potential to improve CV outcomes and the European Society of Cardiology has updated its 2024 ESC guidelines for the management of chronic coronary syndromes and now recommends testing biomarkers of systemic inflammation (hsCRP[1]) to assess residual inflammatory risk and guide treatment, following growing evidence on the role of systemic inflammation in CVD.
- Thyroid disorders are also a risk factor of adverse cardiovascular complications. Early recognition and treatment of thyroid disorders can protect cardiometabolic health of people with thyroid disorders and may reduce some of the associated costs. It is therefore important to raise awareness of thyroid disorders and ensure regular TSH testing among people with CVD.

An integrated approach to screening, that considers the interconnectedness between cardiovascular disease and other conditions such as diabetes, obesity, kidney diseases, thyroid disorders and liver diseases, can deliver better health outcomes.

For example, mortality from CVD can be significantly reduced through better management of metabolic risk factors to prevent secondary cardiovascular events and with a reduction of the time of diagnosis and of provision of care. It is estimated that more than **1 million fatal CVD events could be avoided in the EU over the next 10 years if 70% of people living with CVD had their risk factors better managed than they are today** [18]. Achieving guideline-defined targets and management of risk factors, should be aligned with latest scientific evidence (such as ESC and EAS guidelines) which implementation at the national level should be promoted, supported and measured.

1 mil

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Screening, early diagnosis and timely intervention is not only critically important to reduce preventable CVD, premature deaths and alleviate the burden of CVD, it addresses inequalities in access to prevention across different regions and population groups. Moreover, across a variety of strategies, early CVD detection is predominantly cost-effective[19].

18 Jennifer Gill, Aurelio Miracolo, Konstantina Politopoulou et al (2024). 'How can we Improve Secondary Prevention of Cardiovascular Disease?' London School of Economics and Political Science

19 Oude Wolcherink, M.J., Behr, C.M., Pouwels, X.G.L.V. et al. (2023) Health Economic Research Assessing the Value of Early Detection of Cardiovascular Disease: A Systematic Review. PharmacoEconomics 41, 1183–1203

FLAGSHIP INITIATIVE
Cardiovascular Health Checks

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The health checks would target the widely recognized challenge of costly delays to diagnosis and initiation of guideline-directed prevention and management approaches, and the avoidable worsening of symptoms and conditions which are instead identified in the acute setting.

These health checks can easily be implemented at primary care level where most care is provided for cardiometabolic conditions, due to their low cost (simple bloodwork) and being non-invasive.

During those checks, the following can be measured to offer a good understanding of the risk profile of the individual:

- Family history of premature cardiovascular disease (CVD), Familial Hypercholesterolemia (FH), and cardiomyopathies
- LDL-C (low density lipoprotein cholesterol)
- Blood pressure (heart rate recorded at the time of BP measurement)
- Smoking status and harmful alcohol consumption status
- BMI (body mass index)
- HbA1c (glycated haemoglobin) and history of hyperglycaemia
- Other 'red flag' symptoms, such as oedema, breathlessness, blood/albumin/protein in the urine (haemat/albuminuria/proteinuria) and fatigue
- Elevated levels of Lp(a) (Lipoprotein a)

Based on the results of these checks and the subsequent risk profile assessment of the tested individuals, healthcare professionals could further check for:

- Metrics of abdominal obesity, including waist circumference, waist-to-height ratio, and waist-to-hip ratio
- Blood glucose level, including impaired glucose tolerance and impaired fasting glucose
- Hypothyroidism
- Systemic inflammation
- Impaired kidney and renal function
- Liver disease

Where appropriate based on the initial assessment, basic further diagnostics (e.g. biomarkers such as NTproBNP and ECG) should be made immediately available – ideally on-site – or via rapid referral to specialist centers.

SUPPORTIVE ACTIONS

1. **Support the implementation of the health checks in Member States** through a Joint Action or similar instrument. These should focus on:
    - Healthcare professional (HCP) education and training programs especially within primary care (and relevant specialty care and specialist nursing), to ensure a better understanding of risk factors, (including the role of menopause on cholesterol levels in women) disease interlinks and disease progression in order to optimise early detection and linkage to care.
    - Establishing integrated curricula and certifications to train HCP across Europe will enhance their ability to support patients with CVD, obesity, diabetes, kidney diseases and other metabolic complications in primary care.
    - New diagnostic pathways and community-based multidisciplinary teams that allow for enhanced symptom checks in high-risk groups.
    - Rapid-access enhanced diagnostics (e.g. biomarkers, imaging) supported by clinical governance frameworks, community HCP task delegation, and rapid virtual consultations to reach working diagnoses and initiation of GDMT in as short a time frame as is safe and feasible.
    - Digital solutions, accompanied with healthcare professionals (nurse, pharmacy) skills enhancement to allow opportunistic health checks within existing appointments.
2. **Support for Members States for integration of vaccination in the prevention and management of CVD.** Preventing infectious diseases through life course immunisation is an easy and cost-effective means to prevent not only the burden of disease from the infections targeted, but also the possible repercussions on the cardiovascular system. This would include:
    - Undertake gap analysis and ensure vaccination is incorporated consistently into National CVD Guidelines.
    - Establish protocols for vaccination to be offered routinely during cardiovascular care appointments (e.g., during hospitalisations, outpatient cardiology visits, or heart failure clinic visits).
    - Ensure systems are in place to track vaccination rates among cardiovascular patients, supporting follow-up and targeted interventions for those who are not vaccinated.
    - Concrete targets for the percentage of the population vaccinated against the infections most associated with cardiovascular risk.
    - Training programs dedicated to the role of immunisation as a CVD prevention tool, recognising the European Society of Cardiology Consensus Statement that emphasizes vaccination as a foundational pillar of cardiovascular prevention.

2 Improved management and care for people living with cardiovascular disease

Once patients at risk of CVD have been identified, appropriate and effective treatment and lifestyle interventions must be implemented to deliver on the investment in screening, focusing on achieving evidence-based treatment targets.[20] Access to effective and people-centred prevention, treatment and management of chronic diseases including cardiovascular and cardiometabolic conditions should be based on a robust primary care system; however, cardiometabolic centres of excellence are important to support education and training, medical services and specialised care provision, as well as driving excellence in research. These national centres of excellence can play an important role in developing indicators to be collected in disease and patient registries to enable monitoring, follow-up and treat-to-target strategies, evaluating the effectiveness of prevention and care pathways, and enable pay-for-performance schemes in primary care.

The EU could support and reinforce these activities by establishing a European network that supports and connects cardiometabolic centres of excellence, enabling cross-country capacity building, best practice exchange and benchmarking. This action will improve quality and equity of care across and within EU countries by reducing unwarranted variation in clinical practice and improve the uptake of the latest clinical guidance and innovative solutions.

60%
of patients struggle with adherence.

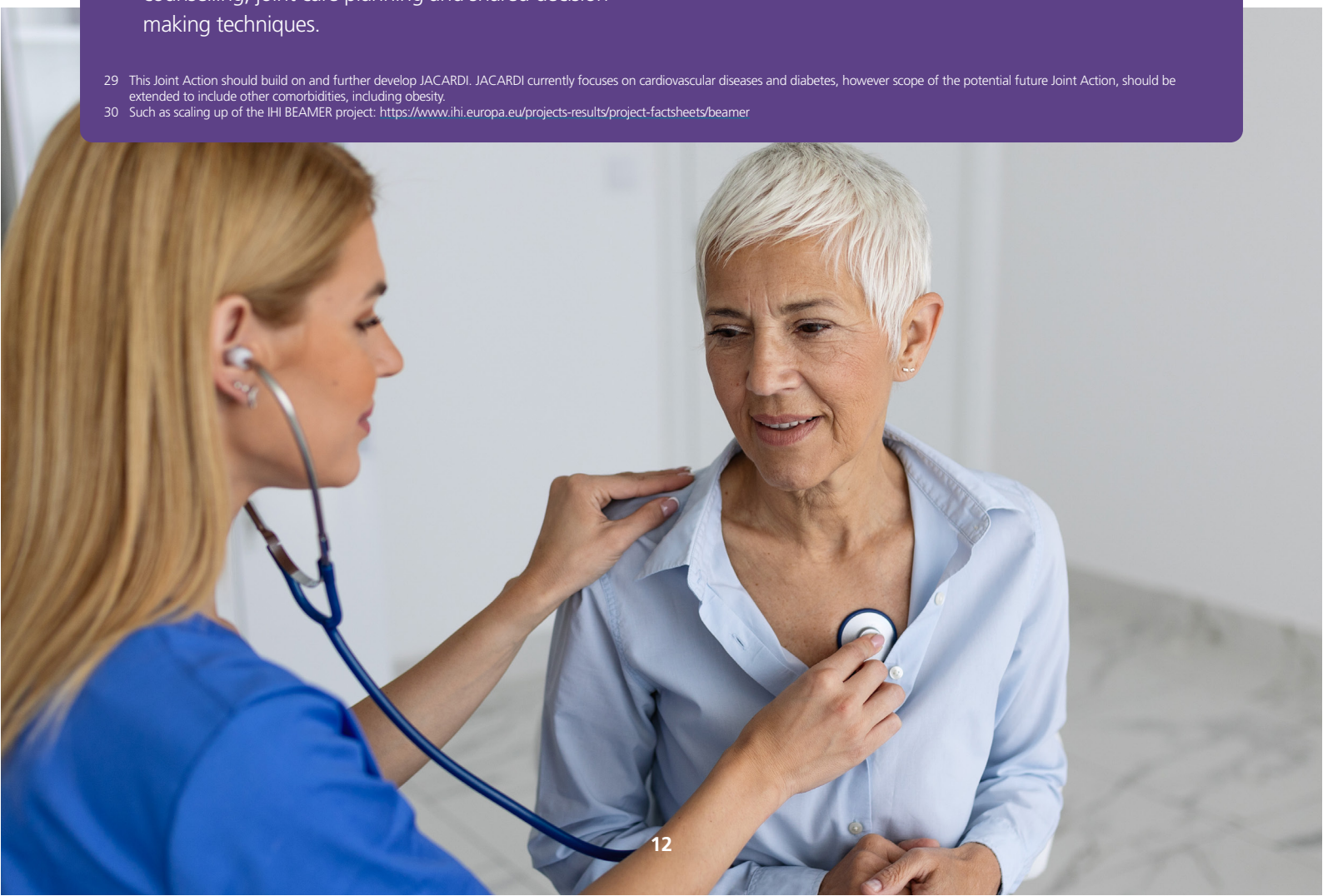
Non-adherence to therapies has a great impact on population health, causing around 200,000 deaths in Europe every year[21 22]. In particular, it has been estimated that more than **60% of patients struggle with adherence**[23] to CV medication and that almost 25% of patients are partially or completely non-adherent to treatment following a discharge from the hospital[24], a number that rises to 40% in non-hospital settings[25]. Non-adherence is extremely costly - In Europe, around €80 to €125 billion is lost annually to non-adherence[26]. Although medications have contributed to a 50% decline in coronary heart disease mortality over the past two decades, high non-adherence rates hinder the full potential of innovative treatments[27]. Improving adherence can enhance patient outcomes, reduce adverse events and mortality, and lessen the burden on health systems while also reducing preventable health issues and their associated social costs for individuals, families, and the healthcare system[28].

20 For hypertension, the treatment goal, based on European Society of Cardiology (ESC) guidelines, is 120 to 129 mm HG with a relaxed goal in the case of treatment intolerance or other complications. (McCarthy CP et al. What Is New and Different in the 2024 European Society of Cardiology Guidelines for the Management of Elevated Blood Pressure and Hypertension? Hypertension. 2025 Mar;82(3):432-444). For elevated cholesterol, the treatment is to obtain the lowest possible LDL-C level by intensifying treatment appropriately. (Guasti L, Lupi A. Lipidology update: targets and timing of well-established therapies. European Society of Cardiology. March 2024.)
21 Baryakova TH, Pogostin BH, Langer R, McHugh KJ.(2023) Overcoming barriers to patient adherence: the case for developing innovative drug delivery systems. Nat Rev Drug Discov. 2023;22(5):387-409. doi:10.1038/s41573-023-00670-0.
22 Van Boven JF, Tsiligianni I, Potočnjak I, et al. (2021) European Network to Advance Best Practices and Technology on Medication Adherence: Mission Statement. Front Pharmacol. 2021;12:748702. Published 2021 Oct 11. doi:10.3389/fphar.2021.748702
23 Kravitz RL, Hays RD, Sherbourne CD, et al. (1993) Recall of recommendations and adherence to advice among patients with chronic medical conditions. Arch Intern Med.
24 Jackevicius Cynthia A, Li P, Tu JV. (2008) Prevalence, predictors, and outcomes of primary non-adherence after acute myocardial infarction. doi: 10.1161/CIRCULATIONAHA.107.706820
25 Laufs, Ulrich, Rettig-Ewen, Volker, Bo, Michael. (2011) Strategies to improve drug adherence. European Hearth Journal
26 International Longevity Centre. (2022) Doctor's orders: Why adherence is critical to improving health outcomes across the life course.
27 Ford ES, Ajani UA, Croft JB, et al. (2007) Explaining the decrease in U.S. deaths from coronary disease, N Engl J Med Jun 7
28 Institut Sapiens. (2023) Améliorer l'adhésion thérapeutique : un enjeu de santé publique

SUPPORTIVE ACTIONS

1. Develop a **European network of integrated CVH centres of excellence across the EU Member States** and support the network through a dedicated Joint Action on cardiometabolic disease prevention and management.[29] The network would: (i) provide education and training for healthcare professionals, supporting cardiometabolic disease management in primary care settings and exchange good practice on integrated care models for cardiometabolic conditions (ii) manage disease registries and develop standardised measurements across EU countries to monitor and benchmark clinical and patient-relevant outcomes, (iii) provide recommendations to improve adherence, (iv) and provide specialised cardiometabolic care for patients across a country or region.
2. **Support Members States to implement treatment adherence programs.** Implement a new generation of patient-centred disease management programmes in chronic CV groups, aiming to boost patient adherence and self-management strategies, via improved therapeutic education, communication skills, psychosocial counselling, joint care planning and shared decision-making techniques. The programs should build on best practice, including methodologies and technologies developed through the Innovative Medicines Initiative/Innovative Health Initiative, and be implemented in collaboration with patients and patient organisations and other relevant stakeholders. This could include support actions to encourage HCPs and patients to monitor therapeutic adherence, supported by digital innovations to track progress and patient outcomes[30], promoting digital health literacy and funding patient education programs, joint care planning and self-management to enable patients to participate in their own care.
3. Building on the success of the Europe's Beating Cancer Plan, **the EU CVH Plan should establish an Inequalities Registry for CVD**, implemented by the Joint Research Centre and bringing together existing cardiovascular registries. This would enable identification of best practices, reduce inequalities in access to CV prevention and care throughout Europe and generate insights into the health outcomes of underserved patient populations.

29 This Joint Action should build on and further develop JACARDI. JACARDI currently focuses on cardiovascular diseases and diabetes, however scope of the potential future Joint Action, should be extended to include other comorbidities, including obesity.
30 Such as scaling up of the IHI BEAMER project: https://www.ihi.europa.eu/projects-results/project-factsheets/beamer



3 Innovation and better ecosystem for clinical trials

Since the development of the first hypertension medicines in the 1960s, cardiovascular health outcomes have seen a major boost with breakthrough discoveries in cardiovascular disease research and development. Some treatment classes in the past have truly revolutionised treatment and risk management for patients either having already suffered from a severe cardiovascular event or with elevated cardiovascular risk factors.

Following improvements in past decades, innovation in CVD is now plateauing with a significant slowdown in the arrival of new CVD treatments on the market[31]. Investment in cardiovascular research has declined due to challenges such as late-stage clinical trial failures, escalating regulatory requirements, and limited patient access post-approval[32]. Looking across all clinical trial phases, cardiovascular drug development had a drop in productivity in 2022, resuming the downward trend reported over the past decade and including a continued low phase III productivity[33]. **Concretely, the cardiovascular therapy area represented only 4% of clinical trials started between 2017-2022**, compared to 26% in oncology[34]. The true investment of bringing one CVD medicine to market, which also includes failures, has been estimated between €3.7-4.6 billion with some investment as much as €11 billion because of several drugs that fail in late-stage clinical trials[35]. This is higher than in many other therapy areas.

the cardiovascular therapy area represented only **4%** of clinical trials started between 2017-2022

These barriers threaten to hold Europe back at the very moment in which our understanding of cardiovascular disease is entering a new era. We now have deeper insights into the underlying mechanisms of complex CV drivers, such as inflammation and the delicate interplay among a number of complex and personal factors, which are set to bring forward new therapies and more personalised approaches to prevention and treatment. To address these challenges, it is imperative to foster an environment that encourages innovation and streamlines the clinical trial process for CV medicines. This includes enhancing data accessibility, integrating advanced scientific approaches into clinical research, and harmonizing regulatory frameworks across EU member states and removing access barriers.

By implementing these strategies, Europe can revitalize its cardiovascular drug development pipeline, ultimately improving health outcomes for millions affected by CVD and related morbidities.

31 https://www.efpia.eu/news-events/the-efpia-view/efpia-news/europe-s-share-of-global-medicines-rd-shrinks-by-a-quarter-in-20-years-as-sector-s-declining-trends-continue/
32 Jackson et al., Improving clinical trials for cardiovascular diseases: a position paper from the Cardiovascular Round Table of the European Society of Cardiology, European Heart Journal, Volume 37, Issue 9, 1 March 2016, Pages 747–754
33 Hwang et al., JACC Basic Translation Sci. 2016, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6113354/ .
34 EFPIA Pipeline Review 2022 https://www.efpia.eu/media/676661/iqvia_efpia-pipeline-review_final-report_public-final.pdf
35 Jackson et. al., Improving clinical trials for cardiovascular diseases: a position paper from the Cardiovascular Round Table of the European Society of Cardiology, European Heart Journal, Volume 37, Issue 9, 1 March 2016, pg. 747–754, https://doi.org/10.1093/eurheartj/ehv213.

SUPPORTIVE ACTIONS

1. Establish a dedicated **CVH Research Mission** and ensure investment in basic and translational research as well as deeper collaboration between stakeholders in order to facilitate an enabling environment for cardiovascular translational research and clinical development, ensuring sustained support across all stages of drug development.
2. Enable the **European network of CVH centres of excellence to support optimisation of clinical development** through multi-stakeholder collaboration and public-private partnerships, including by developing and implementing clinical development tools, novel clinical trial designs and novel use of biomarkers. The network should promote the integration of multi-omics approaches – such as genomics, proteomics and metabolomics – into clinical trials design for CV medicines that may help stratify patients and reduce the uncertainty which tends to inflate the size and duration of clinical trials in the cardiovascular space, as well as encourage the use and acceptance of surrogate endpoints such as biomarkers, and measures of function or symptoms both in regulatory and HTA settings to reduce barriers of drug development without compromising safety or quality.

Additionally, EFPIA believes that structural improvements in the clinical trials ecosystem, as outlined in the Improving EU Clinical Trials: Proposal to Overcome Current Challenges and Strengthen the Ecosystem would benefit CV patients.

4 Utilisation of data and digital health solutions

Digital health solutions are crucial to improve outcomes in CV care and play a role in the prevention, screening and management of CVD[36,37]. The application of digital health to CVH covers a wide array of uses – notably in the fields of disease prevention and early detection, disease management (including self-management, monitoring disease progression and treatment adherence), monitoring and data collection, as well as management of patients' health data and records.

Digital health interventions in CVD prevention and care have the potential to empower patients and providers, improving access to care, long-term outcomes and the overall patient experience, ultimately reducing healthcare costs[38]. Moreover, digital solutions may be a critical factor in enabling key elements of the CVH plan in resource-stressed systems.

However, a range of factors currently hinder the implementation and access to digital health technologies. These factors mostly pertain to social factors (digital divide, digital literacy) technical infrastructure (Internet access, interoperability), data governance (national privacy regulations) and lack of uptake (provider and patients).

Some of the roadblocks to the implementation of digital health interventions in CVD care include[39] the lack of national data privacy and sharing guidelines as well as privacy concerns and individuals' willingness to disclose personal medical information. The lack of national regulations and the inadequacy of legal requirements of digital health instruments (DHIs) are also significant barriers, as is the lack of proper reimbursement for DHIs in some countries.

The collection of clinical data is also crucial to the improvement of outcomes for patients[40] and strictly interlinked to digital health solutions. The aggregation and analysis of health data enable healthcare providers to identify patterns and predict the progression of CVD, leading to more informed clinical decisions, as well as monitor progress and effectiveness of public health, clinical and health service interventions. Health systems generate great amounts of data, whether that be electronic health records or disease registries, though most of it is not used correctly or not used at all[41], leaving huge potential untapped.

Despite the COVID-19 pandemic accelerating the use of data and the adoption of digital health by enabling safe communication between physicians, healthcare providers, and patients, access to health data for scientific research is still subject to various rules and interpretations across EU Members States, limiting its use. However, the implementation of the European Health Data Space provides a golden opportunity to enable and accelerate the sharing of health data for both primary and secondary use, which could greatly enhance both care quality and research in the cardiovascular field.

To harness this potential, the forthcoming EU CVH Health Plan must address existing barriers and promote a conducive environment for the collection of data and the use of digital innovation in cardiovascular health, including interlinked NCDs such as diabetes, obesity and digestive diseases.

36 Islam, S. M. S., & Maddison, R. (2021). Digital health approaches for cardiovascular diseases prevention and management: lessons from preliminary studies. In mHealth (Vol. 7, pp. 41–41). AME Publishing Company. https://doi.org/10.21037/mhealth-2020-6

37 Widmer, R. J., Collins, N. M., Collins, C. S., West, C. P., Lerman, L. O., & Lerman, A. (2015). Digital Health Interventions for the Prevention of Cardiovascular Disease: A Systematic Review and Meta-analysis. In Mayo Clinic Proceedings (Vol. 90, Issue 4, pp. 469–480). Elsevier BV. https://doi.org/10.1016/j.mayocp.2014.12.026

38 Tromp J. et al. World Heart Federation Roadmap for Digital Health in Cardiology. Global Heart. 2022; 17(1): 59

39 Ibid.

40 Hoque DME, Kumari V, Hoque M, Ruseckaite R, Romero L, Evans SM (2017) Impact of clinical registries on quality of patient care and clinical outcomes: A systematic review. PLoS ONE 12(9): e0183667

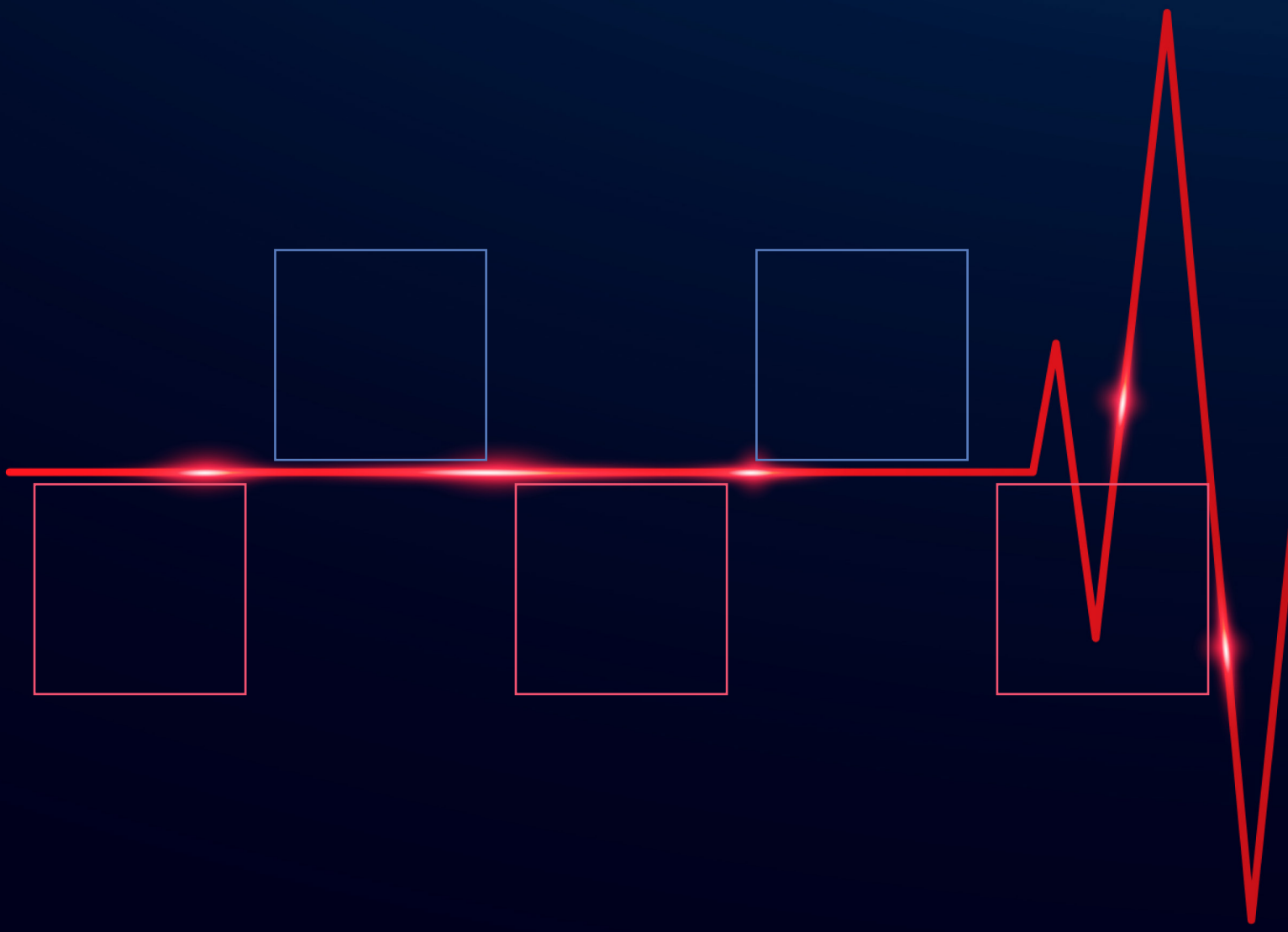
41 Kong, Hyoun-Joong. (2019). Managing Unstructured Big Data in Healthcare System. Healthcare Informatics Research

SUPPORTIVE ACTIONS

- **Scale up existing successful pilots and initiatives in the framework of IMI/IHI to improve cardiovascular disease prevention and management through data and digital tools,** – e.g., to monitor and better manage risk factors, disease progression and observance to treatment in particular in patients at risk (such as diabetes, obesity, and CKD) or living with chronic heart disease (e.g., heart failure) and to support cardiac rehabilitation following acute cardiovascular events, collection of standardised health outcomes data across cardiovascular diseases for use in healthcare quality improvement and research, and tools for self-monitoring and -care. This could be achieved by deploying tools from existing projects such as Health Outcomes Observatory (H2O), COMBINE-CT, EuroHeartPath, GRACE, iCARE4CVD, SEAERCH, UMBRELLA, BigData@Heart.
- **Develop a pilot on cardiometabolic diseases within the European Health Data Space**, linking data from national disease registries and other relevant data sources, which will unlock the potential of big data and novel analytical approaches for CVD research.

FURTHER RESOURCES:

- The case for a joint cardiovascular and diabetes health check
- Towards a new normal: Why boosting CVH health is critical, PwC 2022
- How can we Improve Secondary Prevention of Cardiovascular Disease? LSE 2024
- EFPIA position on EHDS
- EFPIA recommendations on a connected data system in Europe
- Current reference on clinical endpoint derived from Digital Health Technologies



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