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MedTech Europe Cardiovascular Sector Group Policy Proposals for the EU Cardiovascular Health Plan

30/30 EU CVH Plan: Reducing CVD mortality by 30% in 2030

A New Cardiovascular Health Plan for Europe to Address Europe's Leading Cause of Death

APRIL 2025

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Cardiovascular diseases (CVDs) remain the **leading cause of mortality and disability in the European Union** (EU), accounting for approximately 1.7 million deaths in 2021, which represents 32.4% of all deaths.[i] Today, some 60 million Europeans are living with CVD, this is more than the whole of Italy. CVD is also the leading cause of death in women and linked to huge inequalities across geography and socio-economic status too.[ii]

The prevalence of CVDs is anticipated to rise due to factors such as an aging population and increasing prevalence of risk factors like obesity, hypertension, and diabetes. Stroke alone is the leading cause of disability and the second leading cause of death worldwide. Projections indicate a **significant increase in CVD prevalence and mortality by 2050**, underscoring the urgent need for proactive measures. Beyond the profound personal loss, CVDs impose a **substantial economic burden**. The total cost of CVD to the EU economy surged from €210 billion in 2017 to **€282 billion in 2021** — an increase of 34.3% in just four years.[iii,iv] This includes €155 billion in healthcare and long-term care costs, €79 billion attributed to informal care provided by family and friends, and €47 billion due to productivity losses from illness, disability, and premature death. These figures underscore the significant strain CVD places on healthcare systems and the broader economy.

Medical technologies play a central role in the fight against CVD, delivering lifesaving and life-improving innovations that enhance patient outcomes while alleviating financial and operational pressures on healthcare systems. **With CVD costing 11% of total EU health expenditure**, high-quality medical technologies can contribute significantly to cost containment and efficiency gains. As an example, for stroke specifically, recent breakthroughs in prevention and treatment bring potential to cut the burden of stroke in half.[v]

These innovations span the entire patient journey, from early detection and diagnosis to referral, treatment and quality of life and overall they reduce the economic and social burden. For instance, blood tests that identify patients with high cholesterol, high risk of heart attack, and heart failure facilitate early intervention, preventing expensive emergency care and late-stage complications. Modern imaging devices that detect arterial narrowing enable earlier, more targeted treatments, reducing the need for costly invasive interventions. Small cardiac implants such as pacemakers, defibrillators, and trans-catheter technologies help prevent cardiac events, reducing emergency hospital admissions and long-term disability costs. Minimally invasive heart valve and ballon/stent procedures improve clinical, procedural, and patient outcomes and reduce hospitalization times, lower complications, and decrease recurrence rates. Implantable cardiac monitors and associated home monitoring solutions allow for remote patient management, detection of asymptomatic events, minimizing unnecessary hospital visits and easing the burden on healthcare professionals.

Addressing the increasing burden of CVDs demands coordinated action at the EU level. The MedTech Europe Cardiovascular Sector Group, a co-founder and partner of the European Alliance for Cardiovascular Health (EACH), therefore strongly welcomes the 3rd December 2024 adoption of **Council Conclusions on the Improvement of Cardiovascular Health in the EU and the European Commissioner's commitment to adopting a European Cardiovascular Health Plan on the same day**.[vi]

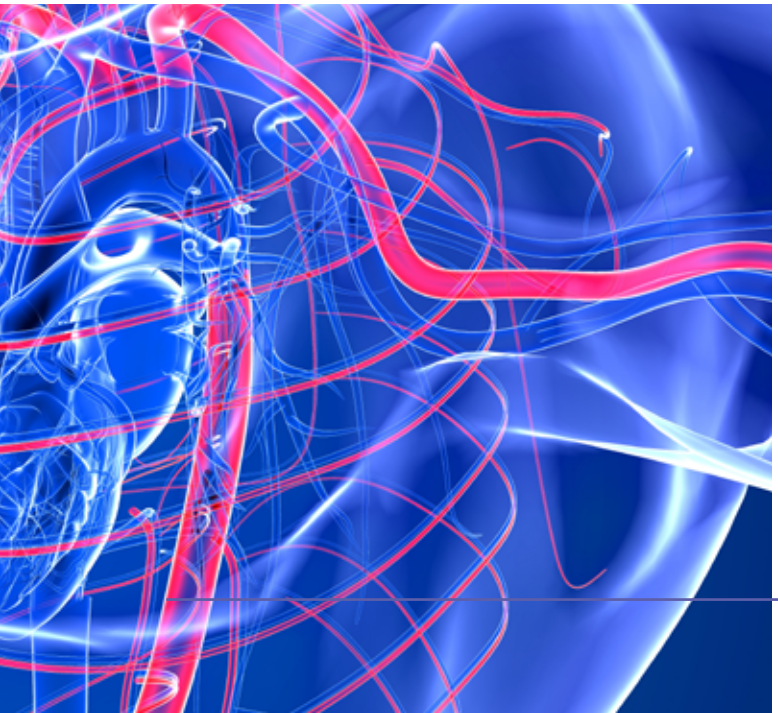
Building on these commitments to tackle the burden of Europe's leading cause of death, the new EU Cardiovascular Health Plan should **contain clear objectives**, and **concrete and ambitious actions** that will tangibly improve people's cardiovascular health and quality of life, reduce the burden of CVD and including stroke, by improved access to detection, referral, treatment and rehabilitation.

From an innovative medical technology industry perspective, the the European Commission has a unique momentum to work on the launch of the EU Cardiovascular Health Plan, and suggests a **launch within one year of the adoption of the Council Conclusions, on 3rd December 2025**. This will acknowledge the EU commitment to tackling the CVD burden, and accelerate access for patients in urgent need.

The CVH Plan should contain a **clear overall objective of reducing premature and preventable CVD-related deaths and disabilities**[vi] **by 30% by 2030 and extending years in good health**. This is in line with the UN Sustainable Development Goals 3.4.[vii]

To achieve this objective, the CVH Plan should prioritize **4 specific actions** to drive equitable patient access across the care continuum, in addition to the already ongoing work on prevention of non-communicable diseases and **invest smartly** to support strong EU coordination and support Member States in effectively reducing the burden of CVDs for patients, their families, the healthcare system, wider society and the economy.

1. **Optimize Patient Pathways from Early Detection, Diagnosis up to Referral and Treatment:** Promoting early detection and timely diagnosis of cardiovascular disease is fundamental to improving outcomes and reducing hospitalizations and long-term care needs. **A European cardiovascular health check program** should be established to ensure systematic screening of at-risk individuals and enable timely referral to specialist care. This must include targeted screening efforts for women, who remain underdiagnosed and undertreated, through gender-sensitive approaches and awareness initiatives. To maximize impact, early detection efforts must be supported by **well-defined EU guidelines for referral pathways** and **integrated care models** to tackle current variability in standards and fragmented referral processes across Member States, complemented by quality and assurance schemes as exists in the European Beating Cancer Plan, and looking at stroke.[viii]



2. **Set an EU Network of Cardiovascular Centers as national and regional hubs of excellence:** Ensuring equitable access to effective cardiovascular interventions and reducing time to treatment is critical to lowering mortality and improving quality of life. To do so, a **European Network of Comprehensive Cardiovascular Centers** should be set up, developing standards to support strengthened hospital infrastructures, and integrating multidisciplinary care delivery. Tackling healthcare workforce shortages through the **integration of technological and procedural innovations** that reduce the CV burden. Special attention must also be given to gender disparities, with a task force focused on ensuring that women receive equal access to care.

3. **Support real-time, evidence-based decision-making, as well as strengthened understanding of disease burden and treatment efficiencies:** To ensure and support real-time and evidence-based decision-making, a **European CVH Knowledge Centre** should be set up, fast-tracking the EU deployment, and integration of existing cardiovascular registries (e.g. SWEDEHEART), and ensuring data harmonization and accessibility in alignment with the European Health Data Space. The EU CVH Knowledge Centre could be in charge of monitoring and assessing the EU CVH Plan implementation and execution with publicly available KPIs and yearly objectives and milestones. A dedicated CV **Inequalities Registry** should be developed to focus on fostering more understanding and support to action to tackling inequalities in gender, geography, and generations.

4. **A Strong EU Innovation Access Policy tailored to CV needs, and strengthening competitiveness:** To achieve tangible reduction of CVD burden, the EU must urgently act to ensure patients have more accelerated access to **medical devices innovation** through more efficient and timely evidence development, regulatory, economic and value assessment, investments, and procurement pathways. This will mean using existing economic cost-benefit evidence to guide investment decisions, ensuring smoother transitions from early feasibility studies to accelerated regulatory access, adaptive health technology assessments, improved value-based procurement systems, and streamlined reimbursement and funding mechanisms.

The ambition of a new EU CVH Plan to reduce the CVD burden by tackling mortality and improving quality of life will only be reachable, if the EU **invests smartly** into its execution. **5 Billion EUR over a period of 5 years** – *less than 2 % of the actual annual economic burden of CVD* – should be landmarked to implement the CVH Plan, and support Member States in their efforts to improve equitable access to detection, referral, treatment, and leveraging the potential of MedTech CV breakthrough, AI, digital, precision medicine innovations to improving efficiencies, reducing burden on hospitals and healthcare workers, and the healthcare system. The EU CVH Plan should also be **measurable and trackable with clear KPIs** and governance, allowing for transparent and structured engagement of all relevant CV stakeholders.

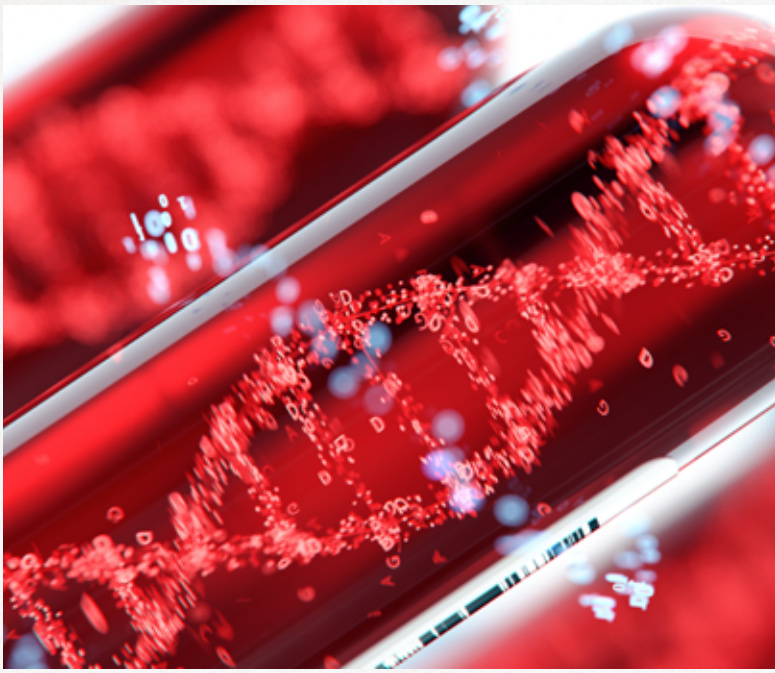
Our Specific Policy Proposals For The EU CVH Plan

POLICY PROPOSAL 1: Optimise Patient Pathways from Early Detection and Diagnosis to Referral and Treatment to improve patient outcomes

Preventing, detecting, and diagnosing cardiovascular conditions early – and managing them efficiently when they occur – is essential to keeping citizens of all ages out of the hospital and in good health, while making efficient use of healthcare resources. Improving secondary prevention in only seven European countries (France, Germany, Italy, Spain, Denmark, Poland, and the UK) could prevent over 670.000 CVD deaths over the next ten years: the EU could leverage so much more benefit from medical technologies to tackle the burden of CVD.[ix]

As indicated in the Council Conclusions of December 2024, the European Commission "should facilitate discussion on better ways to promote systematic screening" and Member States should "scale up secondary prevention through evidence-based cardiovascular health checks that incorporate timely screening, early detection and precision diagnostics tailored to diverse population needs".[x]

Implementation: A European Cardiovascular Health Check Program should be established to ensure early detection and precision diagnosis, with a clear goal of reaching a percentage of at-risk individuals screened for CVD. This could include targeted screening for key cardiovascular risk factors such as blood pressure, cholesterol levels, BMI, PAD, and enable age-appropriate risk assessments, and heart health checks across diverse populations[xi]. Evidence shows that heart checks are not routine across the European population, leading to huge under-detection even in the at-risk population. A third of respondents to a 2019 European survey of people aged over 60 said their primary care physician checked their heart with a stethoscope "occasionally"; only 28% had their heart checked at every visit.[xii]



Leveraging the full spectrum of medical technologies, considered should be (digital) stethoscope checks, blood tests and CV biomarkers, in-vitro diagnostics (IVDs), echocardiography, early detection hand-held devices, and data-driven and AI tools. Thanks to innovative medical technologies, this screening would facilitate timely interventions that improve outcomes and reduce long-term healthcare costs.

By integrating precision medicine and digital/AI health solutions screening effectiveness can be enhanced, whilst reducing healthcare burdens, and optimizing patient outcomes. By incorporating digital tools that support patient preparation for later interventions and

recovery post-treatment, this program would ensure a continuum of care that maximizes efficiency and patient well-being.

The European Cardiovascular Health Check Program can learn and benefit from the experience and organisation already in place for other screening programs such as cancer, as these programs have shown to save lives and improve quality of life.[xiii]

Whilst early detection is a critical component to ensure that citizens are more aware and have an earlier opportunity to enter the care pathways, reaching the objectives of a 1/3 reduction in mortality and disability by 2023, will only be achieved with more effective cardiovascular referral, treatment and after-care.

This will therefore require strong action to **facilitate well-coordinated, optimized and evidence-based care pathways that ensure patients receive the right care, in the right setting, with the right teams, and at the right time.** This means **overcoming the current fragmented referral processes** and uneven standards of care across and within Member States and between CVDs themselves, which are causing to delays in treatment, poorer outcomes, and inefficiencies in healthcare delivery.

Implementation: The European Commission should introduce an initiative to either develop, or facilitate the implementation of existing, European guidelines on optimal CVD and stroke pathways and a quality assurance scheme to define a common set of requirements for cardiovascular and stroke services to improve the quality of care.[xiv] The EU could support Member States at national and regional levels to invest in **comprehensive multidisciplinary training programs for reskilling healthcare professionals** on cardiovascular and stroke care, especially within primary care and amongst specialist nurses. Funding can be secured from the EU Health Programs, Research Framework Programs, and Cohesion Funds within the Multiannual Financial Framework.

To ensure that patient pathways will be tailored to the needs of patients, especially those impacted by inequalities, a dedicated focus should be brought to understanding and tackling these.

The set-up of a **dedicated task force on inequalities** – supported by an Inequalities Registry managed by the Joint Research Centre - should actively come up with **specific actions and recommendations to contribute to closing the inequality gaps, especially in women**, in access across the pathway, including gender-sensitive protocols in screening and with attention to the impact of inequalities in poor access and management of CVD, leading to amputations for some CVDs.[xv] It should also make recommendations about reducing inequalities in access to prevention and treatment across EU Member States.

POLICY PROPOSAL 2: Set-Up an EU Network of Comprehensive Cardiovascular Centres

Lack of investments, inefficiencies in hospital infrastructures and broader healthcare system challenges impact substantially optimal treatment and care of CVD patients. Urgent improvements are needed to ensure stronger coordination, and stronger efficiencies in healthcare delivery, and ensuring health professionals build the skills for the future.

This is especially relevant as healthcare workforce shortage remains a major challenge, impacting waiting times for common elective CV surgeries, which remain high in most OECD countries.[xvi] Medical technology innovations can help release health systems' capacity and enable better care for more patients with existing resources. Such technologies can alleviate the burden of work on healthcare professionals, enhance patient outcomes leading to reduced hospitalisations, ultimately improving outcomes, efficiency and effectiveness and strengthening the resilience of the healthcare systems. Their potential needs to harness and they need to be considered as part of the solution to reducing the CVD burden.

Inspired by the success of the **European Reference Networks (ERNs) and the model established under Europe's Beating Cancer Plan, the European Commission should therefore create a network of Comprehensive Cardiovascular Centres (CCCs) as national and regional hubs of excellence, based on population needs and national infrastructures – and co-funded through EU4Health and Cohesion Funds.**[xvii] This network would build on existing efforts such as accredited stroke units.

Implementation: These centres would help to **improve outcomes by anchoring structured, multidisciplinary care** and ensuring better coordination across care settings. CCCs would also strengthen continuity of care, facilitate equal patient access to timely and effective treatment, and support professional development and knowledge exchange. By integrating care delivery, education, and data, they would contribute to long-term improvements in cardiovascularand stroke health across the EU.

Core responsibilities could include:

- Developing and applying **evidence-based protocols** for detection, intervention, treatment, and rehabilitation.
- Ensuring **timely patient referral and treatment**, as well as cardiac arrest, with shared care models connecting hospitals, primary care, and specialist services.
- Providing **multidisciplinary care** through integrated teams including cardiologists, nurses, rehabilitation specialists, and digital health experts.
- Serving as national hubs for **training and continuous professional development**.
- Collecting and reporting **standardised outcome data** to inform the to-be set up EU Cardiovascular and stroke Registry and support benchmarking and health system improvement.
- Ensure the network facilitates **knowledge exchange** and **best practice sharing**, including through regular collaboration with the Cardiovascular Health Knowledge Centre and other EU-supported networks.
- Prioritise equity by ensuring **geographical distribution** of CCCs includes underserved and remote areas, and by **integrating gender-sensitive care models** into their service delivery frameworks.

Policy Proposal 3: A CVH Knowledge Centre to support real-time decision-making

Reaching the objectives of reducing the burden of CVD, including stroke, with reducing mortality rates and improving quality of life in an equal manner, will also require strong real-life data and evidence. This is critical to allow for real-time and evidence-based policy, decision-making and guidelines development to standardize and optimize care delivery and reduce inequalities in detection and treatment.

Implementation: The set-up of an **EU Cardiovascular Health Knowledge Centre** - in alignment with the European Health Data Space (EHDS) and coordinated by the Joint Research Centre - could serve as the central hub to accelerate the uptake and use of real-world data, facilitate the rapid integration of disease registries, and support data-driven policymaking and prioritization. Taking into consideration interoperability challenges, the Centre should fast-track the EU deployment, and integration of existing cardiovascular registries (e.g. SWEDEHEART), and ensure data harmonization and accessibility.

The EU CVH Knowledge Centre will be in charge of **monitoring and assessing the EU CVH Plan implementation and execution** with publicly available KPIs and yearly objectives and milestones. The CVH Knowledge Centre could also integrate a **Cardiovascular and stroke Inequalities Registry**, providing an inequalities registry in care across Member States to inform policy decisions and funding allocations.

In addition to data, registries, and quality assurance, the Centre should contribute to research innovation through collaboration with in-silico medicine initiatives, using modelling and simulation tools to complement clinical data and support innovation in diagnostics and treatment planning.

The Centre should also collect and share existing evidence about cost-benefits of specific preventive and treatment options, to enable evidence-based policy making.

POLICY PROPOSAL 4: Accelerate CV innovation access pathways from early evidence up to procurement and funding/reimbursement

Timely patient access to breakthrough cardiovascular and stroke innovations is limited across Europe due to fragmented regulatory (IVDR/MDR) pathways, barriers to evidence generation, and lack of uptake quality-driven procurement and reimbursement/funding systems. A streamlined and coordinated EU policy approach is needed to reduce delays and ensure that life-saving technologies are effectively integrated into care.

Implementation: Adopt a harmonised EU methodology for **Early Feasibility Studies** (EFS), based on the Innovative Health Initiative (HEU-EFS) to support early clinical investigations and facilitate faster, safer access to breakthrough CV technologies.[xviii]

Introduce **accelerated regulatory pathways** for medical technologies that address unmet medical needs, building on the EU model used for pharmaceuticals, and for innovative devices in other regions of the world, and leveraging the current revision of the Medical Device / IVDR Regulation.[xix]

Ensure that the implementation of the **EU HTA Regulation** allows for adaptive Joint Clinical Assessments and supports alignment between HTA and public procurement to facilitate access to CV innovations that reduce burden on hospital and healthcare systems. Reform **EU public procurement frameworks** to support value-based purchasing.

The revision of EU public procurement directive should enable quality-driven procurement processes that reward long-term outcomes and system-level efficiency, rather than lowest-cost criteria. Encourage Member States to adopt quality-driven procurement models, including early dialogue with innovators and co-definition of unmet needs, as part of national cardiovascular strategies. Promote **equitable and timely reimbursement of CV diagnostic and therapeutic innovations** across Member States by **supporting innovative payment models** and facilitating the exchange of best practices. Develop and implement evaluation frameworks for digital medical devices (DMDs) that consider real-world effectiveness, broader system value, and long-term benefits to support their uptake and integration into clinical practice.

Investments And Funding Required

To realise the objectives set above and to concretely reduce the CVD burden, it is essential to include cardiovascular health as a priority within EU funding programmes. We therefore suggest **allocating a total of EUR 5 billion over a period of 5 years– which is less than 2% of the current annual CVD burden - to cardiovascular diseases and leveraging multiple EU funding sources** to drive access to detection, referral, treatment, to ensure relevant **investments in infrastructures**, and to support Member States in the **adoption and deployment of innovative solutions that improve outcomes**. This funding should also support a comprehensive mapping of the disease burden and further research, address gender-specific and inequalities.

Funding for the EU CVH Plan should be strategically leveraged from multiple EU sources, including the current **Multiannual Financial Framework (MFF)**, drawing allocations from the **Health Programs, European Regional Development Fund (ERDF) and Cohesion Funds, InvestEU, NextGen EU, and Horizon Europe**, including the **Innovative Health Initiative**, and the **Digital Europe Programme**. The new Multiannual Framework, including the potential competitiveness, AI and other innovation focused funds, should be leveraged towards the implementation of the EU CVH Plan.

- EU4Health, Innovative Health Initiative, ERDF, Cohesion Funds, Next Gen EU, and Digital Europe could focus on early detection efforts and improvements to be made in the patient pathways and supporting actions in terms of infrastructures and the set-up of the Comprehensive Cardiovascular Centres, reskilling of healthcare professionals, the knowledge centre, as well as the introduction of tailored regulatory, assessment and procurement pathways.
- Invest EU and the future Competitiveness Fund could be deployed to **support and co-fund** Member States' efforts to accelerate uptake of innovations.
- Overall, funding should prioritise initiatives that reduce mortality and disability by enabling real-world integration of proven technologies and improving care delivery across the EU, as well as support **breakthrough innovations, digital health, AI-powered diagnostics, remote monitoring, and precision treatments**, ensuring that at least 50% of funded projects involve tangible uptake and health system integration in Member States.

KPIs And Governance

To ensure effective implementation and accountability, a robust governance framework should be established, including mechanisms for monitoring progress, assessing impact, and ensuring stakeholder engagement. This can be achieved through the following measures:

- **Establishment of an EU Cardiovascular Monitoring and Coordination Group:** A dedicated body, working within the framework of the European Health Union, should oversee the implementation of the Cardiovascular Health Plan. This group should include representatives from the European Commission, Member States, patient organizations, healthcare professionals, relevant industry representatives and research institutions to ensure a multi-stakeholder approach.
- **Stakeholder Engagement and Public-Private Collaboration:** Industry stakeholders should play a key role in supporting innovation-driven policy implementation, advising on regulatory and technological advancements, and promoting public-private partnerships to enhance investment in cardiovascular research and innovation. Regular multi-stakeholder dialogues should be organized to align objectives and facilitate knowledge-sharing across Member States.
- **Regular Progress Assessments:** The implementation of the plan should be evaluated through annual progress reports that monitor key performance indicators (KPIs), such as reductions in premature CVD-related mortality and disability, improvements in early detection rates, uptake of innovative treatments, and reductions in regional and gender disparities, with clear target dates. Suggested KPI could be as follows.

Strategic Goal	Target	Monitoring Indicators	Target year
Reduction in CVD Mortality and Disability and extend years in good life	30% reduction in premature deaths and disabilities (aligning with UN SDG 3.4)	Mortality rates from CVD and stroke and years in good health	2030
Early Detection, Diagnosis, Referral and Treatment	EU framework for early detection and Council recommendations Increase in early screening rates among women EU guidelines for patient pathways Set Up Coordinated CV Centres allocating primary and comprehensive specialty centers according to national/regional requirements.	% of at-risk individuals receiving annual heart checks, including PAD Increase of women receiving early screening compared % of high-risk individuals receiving specialist referral after initial screening % of diagnosed patients receiving guideline-based treatment within an optimal timeframe Increase in uptake and deployment of innovations that improve outcomes and reduce CVD burden in hospitals and health centres EU network of CV hospitals covering EU member states	2026: - EU framework and Council recommendations - Coordinated CV Centres set-up 2027: - Pathways guidelines
Innovation Access	Accelerated regulatory pathways for CV Innovations, Adaptive HTA, Uptake of Quality-Driven Procurement and Reimbursement models Set up of Knowledge Centre to enable real-life decision making and understanding of burden, inequalities, and gaps in patient pathways	MDR /IVDR inclusion of accelerated pathways, adaptive HTA deployed, new Procurement Directive includes Quality-Driven Procurement for CV Health Technologies Active Knowledge Centre with accelerated uptake of registries	2026: - MDR revision includes accelerated pathways - Adaptive HTA deployed 2027: - EU PPD includes quality driven CV and stroke technologies 2028: - Active CV Knowledge centre
Investments and Funding for Innovation	€5 billion of total budget allocation earmarked for CVD leveraging multiple EU funding sources.	Total EU funding directed at CVD.	2025 for overall budget allocation

About MedTech Europe and the Cardiovascular Sector Group

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions. The MedTech Europe Cardiovascular Sector Group represents the Cardiovascular Medical Technology Industry, which provides solutions to the burden of CVD on individuals, families and the wider society and economy.

Medical technologies play a central role in the fight against CVD. These innovations, which span the full spectrum of patient care from diagnosis to cure, save lives and add tremendous value to European society. High quality medical technologies are central to Europe's quest for better cardiovascular health and can be found throughout the patient journey, for instance: the blood tests that identify patients with high cholesterol, high risk of heart attack and heart failure; the modern imaging devices that detect narrowing of the arteries, mechanical thrombectomy that can significantly reduce mortality and disability from stroke; the small cardiac implants such as pacemakers, defibrillators and trans-catheter technologies; the implantable cardiac monitors and associated home monitoring solutions; the minimally invasive heart valve and stent procedures that improve clinical, procedural and patient outcomes, while reducing associated costs and recurrence.

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xii) Gaede et al (2020), European heart health survey 2019, https://doi.org/10.1002/clc.23478

xiii) Council recommendations on screening, https://www.consilium.europa.eu/en/press/press-releases/2022/12/09/council-updates-its-recommendation-to-screen-for-cancer/

xiv) These quality assurance schemes were introduced in the European Beating Cancer Plan Flagship 4 initiative, and could draw on models such as the CAPAC accreditation programme in Spain, which aims to standardise post-cardiac arrest management and reduce mortality and disability and neurological damage across hospitals. In collaboration with European Scientific Societies and the Joint Research Centre (JRC), the EU could support the development of certification, and accreditation schemes to establish new guidelines and quality assurance mechanisms to minimize inequalities in access to high-quality early detection, treatment, and care.

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