



EU4Health Programme (EU4H)

Call for proposals

EU4H SANTE Action Grants 2025 EU4H-2026-SANTE-PJ

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CALL FOR PROPOSALS

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0. Introduction

This is a call for proposals for EU **action grants** in the fields of health promotion and disease prevention, cancer, cardiovascular and other non-communicable diseases, health systems and healthcare workforce, digital, other activities under the **EU4Health Programme (EU4H)**.

The regulatory framework for this EU Funding Programme is set out in:

- Regulation 2024/2509 (<u>EU Financial Regulation</u>)¹
- the basic act (EU4H Programme Regulation 2021/5222.

The call invitation is launched in accordance with the 2025 Work Programme³ and will be managed by the **European Health and Digital Executive Agency**, (HaDEA) ('Agency').

The call covers the following **topics**:

- EU4H-2026-SANTE-PJ-01 Call for proposals to pilot and implement cancer screening programmes for gastric cancer (CR/CV&NCD-g-25-12)
- EU4H-2026-SANTE-PJ-02 Call for proposals to pilot and implement cancer screening programmes for lung cancer (CR/CV&NCD -g-25-13)
- EU4H-2026-SANTE-PJ-03 Call for proposals to pilot and implement cancer screening programmes for prostate cancer (CR/CV&NCD-g-25-14)
- EU4H-2026-SANTE-PJ-04 A European flagship initiative leveraging AI and health data for cardiovascular health and related non-communicable diseases: Advancing Risk Prediction, Prevention, Treatments, Personalised Care and Rehabilitation (CR/CV&NCD-g-25-16)
- EU4H-2026-SANTE-PJ-05 Call for proposals on lifelong prevention for a healthy life with focus on cardiovascular diseases (CR/CV&NCD-g-25-18)
- EU4H-2026-SANTE-PJ-06 Call for proposals to support the development of a medicine pricing, reimbursement and access tracker through the EURIPID database (HS-g-25-20)
- EU4H-2026-SANTE-PJ-07 Call for proposals for a programme on orphan medical devices, in particular targeting paediatric patients (HSg-25-24)
- EU4H-2026-SANTE-PJ-08 Call for proposals for health data for biotech innovation leveraging the European Health Data Space (DI-g-25-31)

Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union (recast) ('EU Financial Regulation') (OJ L, 2024/2509, 26.9.2024).

Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027 (OJ L107 of 26 March 2021).

³ Commission Implementing Decision C(2025) 5148 final of 23/07/2025 concerning the adoption of the work programme for 2025 and the financing decision for the implementation of the programme for the Union's action in the field of health ('EU4Health programme').

EU4H-2026-SANTE-PJ-09 - Call for proposals to contribute to the organisation of conferences (OA-g-25-33)

Each project application under the call must address only one of these topics. Applicants wishing to apply for more than one topic, must submit a separate proposal under each topic.

We invite you to read the **call documentation** carefully, and in particular this Call document, the Model Grant Agreement, the <u>EU Funding & Tenders Portal Online Manual</u> and the <u>EU Grants AGA — Annotated Grant Agreement</u>.

These documents provide clarifications and answers to questions you may have when preparing your application:

- the <u>Call document</u> outlines the:
 - background, objectives, scope, activities that can be funded and the expected results (sections 1 and 2)
 - timetable and available budget (sections 3 and 4)
 - admissibility and eligibility conditions (including mandatory documents; sections 5 and 6)
 - criteria for financial and operational capacity and exclusion (section 7)
 - evaluation and award procedure (section 8)
 - award criteria (section 9)
 - legal and financial set-up of the Grant Agreements (section 10)
 - how to submit an application (section 11)
- the <u>Online Manual</u> outlines the:
 - procedures to register and submit proposals online via the EU Funding & Tenders Portal ('Portal')
 - recommendations for the preparation of the application
- the <u>AGA Annotated Grant Agreement</u> contains:
 - detailed annotations on all the provisions in the Grant Agreement you will have to sign in order to obtain the grant (including cost eligibility, payment schedule, accessory obligations, etc).

1. Background

EU4H-2026-SANTE-PJ-01 - Call for proposals to pilot and implement cancer screening programmes for gastric cancer (CR/CV&NCD-g-25-12)

Cancer prevention, screening and early detection offer the best chance of beating cancer and saving lives. The 2003 Council Recommendation on Cancer Screening⁴ in the Union originally endorsed population-based cancer screening for the early detection of breast, cervical and colorectal cancer. On 9 December 2022, a new Council

⁴ Council Recommendation of 2 December 2003 on cancer screening http://data.europa.eu/eli/reco/2003/878/oj.

Recommendation on strengthening prevention through early detection: A new EU approach on cancer screening, was adopted⁵. It is the cornerstone of the new EU Cancer Screening Scheme, one of the flagship initiatives of Europe's Beating Cancer Plan. It aims to ensure that the latest available scientific evidence is reflected, including an extension of screening to prostate, lung, and gastric cancers, based on further research. One of the main instruments to implement the Council Recommendation is the Joint Action EUCanScreen, action CR-g-23-38 of the 2023 EU4Health work programme. Gastric cancer is the tenth most frequent cancer in the Union, and the seventh leading cause of cancer deaths. The incidence is almost twice as high in men as in women, and across Member States, incidence and mortality vary four-fold. This is partially due to different prevalence of risk factors, such as infection with the bacterium Helicobacter pylori. The 2022 Council Recommendation therefore recommends screen-and-treat strategies for H. pylori, including implementation studies, in those countries or regions with high gastric cancer incidence and death rates, taking into account precancerous stomach lesions unrelated to H. pylori infections. Through action CR-g-22-09.03 of the 2022 EU4Health work programme, a first set of projects including pilot studies and further explorative work in the area of gastric cancer screening have been launched such as the project 'Towards gastric cancer screening implementation in the European Union' ('TOGAS'). Through the 2023 and 2024 EU4Health work programmes, preparatory work for the planned Commission Initiative on Gastric Cancer has been initiated, aiming to develop European guidelines and quality assurance schemes for gastric cancer screening and care. To build on this work, and to ensure further roll-out across the EU, further piloting activities and support to implementation at national level will be needed.

This action will support the Europe's Beating Cancer Plan objective to ensure high standards in cancer care and implements the EU4Health Programme's general objective of improving and fostering health in the Union to reduce the burden of communicable and non-communicable diseases (Article 3, point (a), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a), (g) and (i), of Regulation (EU) 2021/522.

EU4H-2026-SANTE-PJ-02 - Call for proposals to pilot and implement cancer screening programmes for lung cancer (CR/CV&NCD -g-25-13)

Cancer prevention, screening and early detection offer the best chance of beating cancer and saving lives. The 2003 Council Recommendation on Cancer Screening⁶ in the Union originally endorsed population-based cancer screening for the early detection of breast, cervical and colorectal cancer. On 9 December 2022, a new Council Recommendation⁷ on strengthening prevention through early detection: A new EU approach on cancer screening was adopted. It is the cornerstone of the new EU Cancer Screening Scheme, one of the flagship initiatives of Europe's Beating Cancer Plan. It aims to ensure that the latest available scientific evidence is reflected, including an extension of screening to prostate, lung, and gastric cancers, based on further research. Lung cancer is the second most diagnosed cancer in men, and the third in women. It is the leading cause of cancer death for men, and the second for women. Lung cancer mortality and five-year-survival rates vary significantly across the Union. The Council Recommendation encourages exploring the feasibility and effectiveness of lung cancer screening programmes with low-dose computed tomography, starting with

⁵ Council Recommendation of 9 December 2022 on strengthening prevention through early detection: A new EU approach on cancer screening replacing Council Recommendation 2003/878/EC (OJ C 473, 13.12.2022, p. 1).

⁶ Council Recommendation of 2 December 2003 on cancer screening http://data.europa.eu/eli/reco/2003/878/oj.

⁷ Council Recommendation of 9 December 2022 on strengthening prevention through early detection: A new EU approach on cancer screening replacing Council Recommendation 2003/878/EC (OJ C 473, 13.12.2022, p. 1).

individuals at high risk such as heavy smokers and ex-smokers, also taking into account primary and secondary prevention approaches such as smoking cessation. Artificial Intelligence based solutions and approaches can help roll-out lung cancer screening programmes in the Member States, however the approach needs to be scientifically sound and supported by scientific evidence. Through action CR-g-22-09.02 of the 2022 EU4Health work programme, a first set of projects including pilot studies and further explorative work in the area of lung cancer screening, such as 'Strengthening the screening of lung cancer in Europe' ('SOLACE') has been launched.

Through the 2023 EU4Health work programme, preparatory work for the planned Commission Initiative on Lung Cancer has been initiated, to develop European guidelines and quality assurance schemes for lung cancer screening and care. Under the Digital Europe programme, Cancer Image Europe platform is deployed which supports collaborative multi-centric studies on AI in cancer. To build on this work, and to ensure further roll-out of lung cancer screening across the Member States, further piloting activities and support to implementation at national level will be needed.

This action will support the Europe's Beating Cancer Plan objective to ensure high standards in cancer care and implements the EU4Health Programme's general objective of improving and fostering health in the Union to reduce the burden of communicable and non-communicable diseases (Article 3, point (a), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a), (g) and (i), of Regulation (EU) 2021/522.

EU4H-2026-SANTE-PJ-03 - Call for proposals to pilot and implement cancer screening programmes for prostate cancer (CR/CV&NCD-g-25-14)

Cancer prevention, screening and early detection offer the best chance of beating cancer and saving lives. The 2003 Council Recommendation on Cancer Screening⁸ in the Union originally endorsed population-based cancer screening for the early detection of breast, cervical and colorectal cancer. On 9 December 2022, a new Council Recommendation⁹ on strengthening prevention through early detection: A new EU approach on cancer screening was adopted. It is the cornerstone of the new EU Cancer Screening Scheme, one of the flagship initiatives of Europe's Beating Cancer Plan. It aims to ensure that the latest available scientific evidence is reflected, including an extension of screening to prostate, lung, and gastric cancers, based on further research. Prostate cancer is the most common cancer in men, and the third cause of cancer death. Mortality rates vary threefold across the Union. The 2022 Council Recommendation recommends, in view of the significant amount of ongoing opportunistic screening, to evaluate the feasibility and effectiveness of the implementation of organised programmes on the basis of prostate-specific antigen ('PSA') testing for men, in combination with additional magnetic resonance imaging ('MRI') scanning as a follow-up test. Artificial Intelligence based solutions and approaches can help roll-out prostate cancer screening programmes in the Member States, however the approach needs to be scientifically sound and supported by scientific evidence. Through action CR-g-22-09.01 of the 2022 EU4Health work programme, a first set of projects including pilot studies and further explorative work in the area of prostate cancer screening, such as 'Prostate cancer awareness and initiative for screening in the European Union' ('PRAISE-U') has been launched. Through the 2023 EU4Health work programme, preparatory work for the Commission Initiative on Prostate Cancer has been initiated, to develop European guidelines and quality assurance schemes for prostate cancer screening and care. Under the Digital Europe

⁸ Council Recommendation of 2 December 2003 on cancer screening http://data.europa.eu/eli/reco/2003/878/oj.

⁹ Council Recommendation of 9 December 2022 on strengthening prevention through early detection: A new EU approach on cancer screening replacing Council Recommendation 2003/878/EC (OJ C 473, 13.12.2022, p. 1).

programme, Cancer Image Europe platform is deployed which supports collaborative multi-centric studies on AI in cancer. To build on this work, and to ensure further roll-out of prostate cancer screening across the Union, further piloting activities and support to implementation at national level will be needed.

This action will support the Europe's Beating Cancer Plan objective to ensure high standards in cancer care and implements the EU4Health Programme's general objective of improving and fostering health in the Union to reduce the burden of communicable and non-communicable diseases (Article 3, point (a), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a), (g) and (i), of Regulation (EU) 2021/522.

EU4H-2026-SANTE-PJ-04 - A European flagship initiative leveraging AI and health data for cardiovascular health and related non-communicable diseases: Advancing Risk Prediction, Prevention, Treatments, Personalised Care and Rehabilitation (CR/CV&NCD-g-25-16)

In the Union, non-communicable diseases ('NCDs') are responsible for approximately 86% of all deaths placing a significant burden on citizens' lives, health systems, and economies.

Cardiovascular diseases ('CVDs') are the single largest contributor to the NCD burden, causing over 3.9 million deaths annually in Europe and more than 6 million new cases each year in the Union alone. Often coexisting with or driven by comorbid diseases like cancer, cancer treatments, or conditions such as diabetes, obesity, metabolic disease, and hypertension, they represent not only a clinical endpoint but also a sentinel for wider chronic disease and morbidity risk.

In this context, cardiovascular health becomes a proxy for broader metabolic and chronic health, shaped by genetic predispositions, social and environmental determinants, and modifiable risk factors, such as unhealthy diet linked poor nutrition, and the high intake of salt, sugar and saturated fat or highly processed food. Preserving cardiovascular health means intervening early and intelligently to prevent disease escalation across the spectrum of interrelated NCDs.

Yet, despite well-established clinical knowledge on risk factors, most CVDs and related conditions remain undetected until late stages, often when irreversible damage has occurred. The current fragmentation of health data, coupled with limited deployment of Artificial Intelligence ('AI') solutions, hampers timely, targeted, and scalable interventions.

CVDs represent a strategic area for Union action — not only due to their epidemiological weight, but also because of their relatively high predictability and preventability. Advances in health data infrastructure and AI create new opportunities to detect early signals, identify individuals at risk, enable personalised prevention and treatment, and empower citizens to better manage their condition.

Rapid progress in AI including in medical imaging, predictive analytics, and personalised interventions, has demonstrated strong potential to transform the early detection and prevention of NCDs, including cancer, and now **cardiovascular and related metabolic diseases**. However, the deployment and scale-up of AI tools remain limited across Member States, due to challenges in **data access and quality**, **limited clinical integration**, and a lack of **continuous performance evaluation** in real-world healthcare settings.

The Union is actively promoting trustworthy AI in healthcare with a variety of initiatives such as building a regulatory framework conducive for innovation (e.g. Regulation (EU)

2025/327 of the European Parliament and of the Council on the European Health Data Space, Regulation (EU) 2024/1689 of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (AI Act), Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, and Regulation (EU) 2019/881 of the European Parliament and of the Council on ENISA and on cybersecurity certification (Cybersecurity Act)) as well as targeted innovation promotion measures such as the GenAIEU initiative and AI Factories. Dedicated Union funding programmes (e.g. EU4Health Programme, Digital Europe Programme, Horizon Europe) support the development and deployment of AI solutions in healthcare in the Union.

Integration of genomic insights into AI models and tools could help discern the complex impact of multiple genetic mutations on an individual's predisposition to CVDs and related NCDs, contributing to mitigating the risk of an early onset and severe course of the disease by triggering preventive measures. Moreover, in-silico modelling and virtual human twin technologies could offer relevant synergetic opportunities. AI has the potential to improve the efficiency and effectiveness of healthcare systems, enhance patient outcomes, and reduce healthcare costs.

Despite rapid innovation, many AI solutions still lack real-world validation, remain under-deployed and are even less frequently scaled-up across the Union's diverse healthcare systems. The challenges are multifaceted, including the limited access to good quality and representative data, insufficient skills, low acceptance, and clinical or organisation workflows that are not ready for the integration of such AI tools. Fragmented regulatory frameworks and the lack of continuous clinical performance evaluation further hamper the ability to ensure that AI systems perform equally well in diverse healthcare environments and are appropriately deployed into clinical practice.

The European Health Data Space ('EHDS')¹⁰ facilitates secure and privacy-preserving access to health data across the Union, supporting research and innovation such as the development of AI-powered cardiovascular applications. By streamlining access to representative health data from Europe's population, the EHDS can enable the creation of more accurate and effective AI models and support the scaling up of AI solutions across the Union. As part of the Commission broader efforts to promote AI in healthcare (as described in the section "Synergies/links with other EU programmes") initiatives such as the 1+ Million Genomes, the European Virtual Human Twins, and Cancer Image Europe can provide valuable synergies. Integration of genomic insights into AI models and tools could help discern the complex impact of multiple genetic mutations on an individual's predisposition to CVDs, contributing to mitigating the risk of early onset and severe progression of the disease by triggering preventive measures. Moreover, in-silico modelling and virtual human twin technologies could offer relevant synergetic opportunities. This initiative aims to ensure comprehensive AI adoption in medicine, balancing technological innovation, clinical practice, and regulatory frameworks to deliver high-quality, safe, and effective care.

This initiative aims to enable responsible and widespread adoption of mature AI applications for cardiovascular health and related non-communicable diseases in clinical practice, by addressing deployment conditions, generating real-world evidence, and promoting high-quality, standards-based implementation. It seeks to create the conditions for scaling-up well-performing AI models in line with EU values, clinical needs, and data protection requirements. The facilitation of an accelerated and regulated uptake of AI solutions offers strategic opportunities to advance these broader goals and to help to reduce the burden of cardiovascular diseases, which remain a leading cause of death and disability in the Union. This action does not aim at developing new AI technologies, but at supporting the conditions for their responsible and scalable adoption in healthcare systems. It focuses on testing mature AI tools in

¹⁰ https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space en.

real-world settings, producing evidence-based deployment protocols, and overcoming barriers to safe, effective and equitable integration of such tools in clinical workflows.

This action will build on synergies with the 'Advancing the adoption of AI in health' action DIg-24-76 under 2024 EU4Health work programme, ensuring alignment in objectives and leveraging findings, particularly regarding good deployment practices for AI in healthcare. The synergies with relevant actions, including on genomics, funded under EU4Health, Digital Europe and Horizon Europe programmes are key to enhancing the collective efforts to promote AI in healthcare.

It supports the development, validation and adoption of AI solutions in healthcare based on European data, in compliance with EU regulatory frameworks. This strengthens the Union's capacity to rely on trustworthy, high-performing AI solutions tailored to its healthcare needs, and reduces dependency on non-EU technologies and datasets.

This action implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3, point (a), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, point (a) and (f), of Regulation (EU) 2021/522.

EU4H-2026-SANTE-PJ-05 - Call for proposals on lifelong prevention for a healthy life with focus on cardiovascular diseases (CR/CV&NCD-g-25-18)

Europe is facing a huge challenge related to its ageing population and the impact on society. A significant rise in life expectancy has been observed across Member States in the last decades. Improvements in living and social conditions, advancements in health care and general economic progress have all led to an increasing number of European citizens living longer lives. As a result, many of them have to manage multiple morbidities at the same time.

Europe's population is ageing and that comes with consequences for health services and policy, including on healthy longevity, due to the rising burden of noncommunicable diseases, such as cardiovascular diseases and neurodegenerative disorders¹¹. In fact, non-communicable diseases, such as cardiovascular diseases and diabetes, represent 80% of the health burden. This burden can best and most efficiently be addressed via prevention, through which 70% of it can be avoided. Therefore, it is essential to support Member States and citizens in this area as it is the core of the health and financial burden of disease. Prevention efforts must therefore be ramped up through the entire lifespan, starting with pregnancy and early childhood and reaching out to the elderly supporting healthy longevity. Cardiovascular diseases remain the leading cause of premature death in the Union and were estimated to cost the Union EUR 282 billion in 2021¹². More than 6 million new cases of cardiovascular diseases are diagnosed in the EU each year and almost 49 million people are living with the disease. It is estimated that around 32 million people in the Union are living with diabetes, with 90% of cases being type 2 diabetes which is largely preventable. These figures underscore the substantial burden that cardiovascular diseases place on individuals, health systems and economies within the Union. The data highlights the need for continued focus on prevention, early diagnosis, treatment and care within the Union.

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¹¹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on The European Health Union: acting together for people's health (COM(2024)206 final).

¹² European Heart Journal, Volume 44, Issue 45, 1 December 2023, Pages 4752–4767.

Although the OECD¹³ has made a strong case for increasing spending on health promotion and disease prevention measures as it is cost-effective, health spending remains overwhelmingly focused on curative care, with only 3% of total health spending going toward prevention on average. (2017, 2022 OECD "Health at a Glance" reports)¹⁴.

The State of Health 2023 synthesis report¹⁵ highlights that a multi-sectoral approach is needed to tackle health inequalities and that investments in public health, disease prevention and health systems should remain a key priority in the medium term. The 2024 OECD "Health at a Glance" report¹⁶ recommends prioritising prevention throughout the life course and empowering individuals to manage their own health.

A comprehensive, cross-cutting, multi-sectoral and lifelong prevention approach to healthy longevity, that is evidence-based, is needed to support individuals' potential for healthy longevity. Such an approach includes health promotion and disease prevention strategies targeting in particular children and young people, with initiatives aimed at improving nutrition, physical activity, and mental well-being. This will also include early detection, as appropriate, improving integrated patient pathways, enhancing the quality of life of patients, and addressing multimorbidity and specific disease-related challenges. Prevention should also focus on systemic and population-wide measures and not unfairly place all the burden on individual choices. Therefore, a cross-cutting approach to healthy longevity and lifelong prevention should go beyond public health and strongly include other key policy areas such as environment, housing, employment, etc.

This approach aims to reduce the burden of non-communicable diseases, such as cardiovascular diseases, diabetes, and neurodegenerative disorders, and related risk factors, and to promote healthy lifestyles at every stage of life. This is key to adding healthy life years and must consider the determinants of health, including commercial, environmental and socio-economic determinants.

The objective of a healthy lifespan for all and of a healthier ageing population brings opportunities and challenges for Member States that will only grow in importance in the future. Broad ranging policy and legislative changes at Union and national level are needed to react to both long-standing and new and emerging challenges in an ageing population. Union supports can be decisive to achieve these purposes. The Expert Group on Public Health (PHEG) identified the main priorities and actions on public health challenges for the period 2024-2026. Health promotion and socio-economic determinants of health were considered to be the most relevant, followed by mental health, cancer and the prevention of non-communicable diseases in general, and cardiovascular diseases in particular. Working on vaccine-preventable diseases and vaccination was also identified as a priority. The priorities of the PHEG focused on mental health, and on health promotion and prevention of non-communicable diseases in 2024. The focus of the PHEG in 2025 will be on healthy longevity, lifelong prevention of diseases, including cardiovascular diseases, vaccine-preventable diseases, and vaccination, as well as specific communicable diseases, such as TB, HIV/AIDS and hepatitis. The Commission will support the collection of best and promising practices via the EU Best Practices Portal.

This action supports the "Healthier Together – EU Non-communicable diseases initiative" and Europe's Beating Cancer plan and implements the EU4Health Programme's general objective to improve and foster health in the Union and to strengthen health systems by improving their resilience and resource efficiency (Article

¹³ How much do OECD countries spend on prevention?", OECD Health Working Papers, No. 101, OECD Publishing, Paris, https://doi.org/10.1787/f19e803c-en.

¹⁴ Health at a Glance: Europe - European Commission (europa.eu).

¹⁵ State 2023 synthesis-report en.pdf (europa.eu).

¹⁶ Health at a Glance: Europe 2024 - European Commission.

3, point (a), of Regulation (EU) 2021/522), through the specific objective defined in Article 4, point (a), of Regulation (EU) 2021/522.

EU4H-2026-SANTE-PJ-06 - Call for proposals to support the development of a medicine pricing, reimbursement and access tracker through the EURIPID database (HS-g-25-20)

Pricing and reimbursement decisions influence access to cost-effective and affordable medicines. The Pharmaceutical Strategy for Europe notes that the Commission will foster transparency of price information to help Member States take better pricing and reimbursement decisions. It also commits to support mutual learning between national authorities, including on coverage of pharmaceutical costs and price increase criteria. The Draghi Report on the future of European competitiveness¹⁷ highlighted the need for coordinated actions on pricing and reimbursement of medicines, including through databases such as the European Integrated Price Information Database ('EURIPID').

Contributing to these objectives, EURIPID is a voluntary non-profit collaboration of the Union's pricing and reimbursement authorities, sharing information on pharmaceutical pricing policies and prices of medicinal products.

The recent OECD Health Working Paper co-funded by the Commission, on exploring the feasibility of monitoring access to medicines¹⁸ concluded that whilst affordable access is a policy priority, systematic monitoring of its various dimensions is lacking and leveraging data captured in existing platforms such as EURIPID could aid systematic data collection and analysis.

This action implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products, medical devices, and crisis relevant products in the Union (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (c) and (f), of Regulation (EU) 2021/522.

EU4H-2026-SANTE-PJ-07 - Call for proposals for a programme on orphan medical devices, in particular targeting paediatric patients (HS-g-25-24)

Medical devices and *in vitro* diagnostics have a fundamental role in saving lives by providing innovative healthcare solutions for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of many diseases, including non-communicable diseases such as cancer, cardiovascular diseases or diabetes.

Medical devices are subject to Regulation (EU) 2017/745¹⁹, while *in vitro* diagnostic medical devices are subject to Regulation (EU) 2017/746²⁰.

For the purpose of this action, orphan devices are medical devices, including *in vitro* diagnostic medical devices, that benefit a relatively small group of patients in the treatment or diagnosis of a disease or condition and where no or only insufficient

¹⁷ The future of European competitiveness, Part A | A competitiveness strategy for Europe and The future of European competitiveness, Part B | In-depth analysis and recommendations.

¹⁸ Exploring the feasibility of monitoring access to novel medicines: a pilot study in EU Member States, OECD 2023.

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

²⁰ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

suitable alternative therapeutic or diagnostic options with expected similar clinical benefit and safety exist. Criteria for orphan devices are specified in guidance MDCG 2024-10 *Clinical evaluation of orphan medical devices*²¹.

The need to consider the specificities of orphan devices has been repeatedly highlighted as an area of priority by the Commission as well as by the Member States²² and the European Parliament²³.

At the Union level, no specific legislation exists regarding the development and/or the market access of orphan devices which are in a large part intended for paediatric patients.

The level of clinical evidence that is required to place medical devices on the market has been increased by the MDR, including an increased need for pre-market clinical investigations for certain higher risk devices to verify their safety and clinical performance. These increased clinical evidence requirements present a challenge for devices specifically intended for use in rare diseases/conditions, or in specific indications for rare cohorts of patients with an otherwise non-rare disease/condition. In many cases, orphan devices are intended for use solely or predominantly in minors and paediatric populations, and/or in emergency situations. Proactively generating clinical data within an appropriate time in small patient populations is particularly challenging, as is the case for vulnerable populations in light of the ethical and regulatory requirements to appropriately protect these populations, as well as greater practical challenges of performing clinical studies in certain cohorts such as infants and children.

Paediatric patients usually differ from adults in terms of their size, growth, development, body chemistry, and disease propensity, adding to the challenges of paediatric device development. Costs related to market access, in particular clinical evaluation and conformity assessment, often render the development of paediatric devices economically not interesting. Innovation for paediatric patients therefore lags behind the advances made for adult devices.

This action implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products, medical devices, and crisis relevant products (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a), (c) and (h), of Regulation (EU) 2021/522.

EU4H-2026-SANTE-PJ-08 - Call for proposals for health data for biotech innovation leveraging the European Health Data Space (DI-g-25-31)

The intersection of health data and artificial intelligence ('AI') is poised to accelerate breakthroughs in the biotechnology ('biotech') industry, with the potential to transform human health, drive economic growth, and foster innovation. The EU, with its unparalleled talent pool, innovative industries, and robust regulatory frameworks, is strategically positioned to capitalize on this opportunity to also achieve the ambition of an AI continent. However, the biotech sector faces significant challenges, including the need for high-quality data, secure data access frameworks, streamlined regulatory processes, overcoming deploying challenges and enabled to scale up.

²¹ MDCG 2024-10 Clinical evaluation of orphan medical devices.

²² Council conclusions on the Future of the European Health Union: A Europe that cares, prepares and protects (11597/24).

²³ Resolution on the urgent need to revise the Medical Device Regulation (2024/2849 (RSP)), October 2024.

⁹⁶ 2023 EU4Health Work Programme.

Regulation (EU) 2025/327 on the European Health Data Space ('EHDS') is a key initiative that aims to address some of these challenges by providing a secure and efficient framework for health data access and reuse across the Union. Furthermore, European data sharing and research infrastructures play a crucial role in facilitating access to high-quality health data, particularly in the fields of genomic, cancer, and brain research. The federation of these infrastructures is essential for supporting innovation, driving discovery, and knowledge promotion.

Building on this foundation, to unlock the full potential of the biotech sector, it is essential to support a coordinated approach on how to leverage health data and research infrastructures (and in particular genomics, cancer datasets, metabolomics studies, proteomics databases, and clinical trial networks) in the context of the EHDS frameworks to accelerate and promote innovation. This will enable the unlocking of new opportunities for innovation, drive growth, and improve health outcomes across the Union To fully harness the potential of the biotech sector, collaboration with the EU's AI Factories will be pivotal. These AI factories can act as incubators for innovation, enabling the integration of health data insights with AI capabilities to create next-generation biotech solutions.

This action implements the EU4Health Programme's general objective of strengthening health systems (Article 3, point (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a) and (f), of Regulation (EU) 2021/522.

EU4H-2026-SANTE-PJ-09 - Call for proposals to contribute to the organisation of conferences (OA-g-25-33)

The work programme will support the organisation of Union-wide conferences which will meet the objectives of Regulation (EU) 2021/522.

There is a need to timely identify upcoming health challenges and involve a broad range of stakeholders such as citizens, patients, practitioners, scientists, policy makers from local, regional, and Union level, in finding possible solutions and alternative ways to address such health challenges; to provide information to individuals for preventing and responding to diseases; to join efforts with the beneficiaries of the Union funds to inform and communicate about the actions implementing the EU4Health Programme and the results obtained.

One of the ways to achieve this is by reaching out to the public and all relevant stakeholders in high level science-policy-society events that provide the optimal forum to facilitate the exchange of ideas (e.g. scientific evidence and good practices) and the development of feasible solutions..

The action will support the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3, points (a) to (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a) to (j), of Regulation (EU) 2021/522.

2. Objectives — Themes and priorities — Activities that can be funded — Expected impact

EU4H-2026-SANTE-PJ-01 - Call for proposals to pilot and implement cancer screening programmes for gastric cancer (CR/CV&NCD-g-25-12)

Objectives (linked to general and specific objectives of the programme)

This action will contribute to the implementation of gastric cancer screening programmes, in a stepwise approach to ensure the gradual and appropriate planning, piloting, and roll-out of the screening programmes within national priorities, as called for in the 2022 Council Recommendation on cancer screening. The use of AI in ongoing (pilot) programmes shall be assessed, and the potential use of AI, where feasible, further be explored. Potential synergies with the project stemming out of the "Call for proposals on advancing the adoption of artificial intelligence in health" (DI-g-24-76 of 2024 EU4Health work programme) shall be explored.

Activities that can be funded (scope)

The action may include the following activities:

- facilitating implementation research via new pilots and programme rollout initiatives through:
 - o monitoring and assessment of on-going implementation studies;
 - defining needs for and planning of new implementation studies based on gap analyses, building on deliverables of the TOGAS project; supporting, coordinating and running implementation studies within Member States;
 - linking regional/national implementations studies within Member States to reduce duplication and human/financial resources as well as to increase study impact;
 - regular quality assessment and improvement of implementation research.
- collection and assessment of benefits/harms data and other data on outcomes, quality assurance and cost-effectiveness relating to gastric cancer screening programmes from the national level based on the established methods, infrastructure, and networks within the previous EU4Health Programme funded projects;
- linking relevant experts and representatives from European medical societies and patient organisations to ensure broad outreach to corresponding national partner societies and patient organisations;
- effective dissemination as well as bidirectional knowledge exchange with all Member States relating to gastric cancer screening;
- close collaboration with related projects, such as those covering lung and prostate cancer screening, and the Joint Action Implementation of cancer screening programmes ('EUCanScreen')²⁴ from the 2023 EU4Health work programme action CR-g-23-38; and
- close collaboration with the Commission's Joint Research Centre, and the alignment with the outputs of the planned Commission Initiative on Gastric Cancer; and
- exploration of the potential of AI in gastric cancer screening.

Specific action-level indicators for reporting purposes

- Number of Member States providing information on gastric cancer screening pilot programmes or implementation studies
- Number of experts selected for the gastric cancer screening network
- Number of Member States enrolled in gastric cancer screening implementation studies within the project

²⁴ 2023 EU4Health Work Programme

• Number of citizens recruited for the implementation studies within the project

Expected impact (including EU added value, expected outputs and results)

- regularly updated reporting and gap analysis to guide Member States;
- enhanced knowledge on the current state and feasible and successful modalities
 of gastric cancer screening programmes, including the integration of new AIbased screening technologies to improve detection and reduce disparities across
 Member States;
- further roll-out of gastric cancer screening;
- further availability of gastric cancer screening programmes in relevant Member States based on European Guidelines, as available.

<u>Type of applicants targeted</u>: Public authorities, research organisation, civil society organisations, ERNs, academia and education establishments, hospitals, international organisations, networks in field of health.

EU4H-2026-SANTE-PJ-02 - Call for proposals to pilot and implement cancer screening programmes for lung cancer (CR/CV&NCD -g-25-13)

Objectives (linked to general and specific objectives of the programme)

This action will contribute to the implementation of lung cancer screening programmes, to enhance early detection and programme efficiency. The gradual and appropriate planning, piloting, and roll-out of the screening programs will align with national priorities and the latest scientific advancements as called for in the 2022 Council Recommendation on cancer screening. The use of AI in ongoing (pilot) programmes shall be assessed, and the potential use of AI, where feasible, further be explored. Synergies with actions implementing the European Cancer Imaging Initiative, in particular the Cancer Image Europe platform, shall be explored. Potential synergies with the project stemming out of the "Call for proposals on advancing the adoption of artificial intelligence in health" (DI-g-24-76 from the 2024 EU4Health Work Programme) shall be explored.

Activities that can be funded (scope)

The action may include the following activities:

- facilitating implementation research via new pilots and rollout initiatives through:
 - o monitoring and assessment of on-going implementation studies.
 - defining needs for and planning of new implementation studies based on gap analyses, building on deliverables of the SOLACE project.
 - supporting, coordinating and running implementation studies within Member States; o linking regional/national implementations studies within Member States to reduce duplication and human/financial resources as well as to increase study impact.
 - regular quality assessment and improvement of implementation research.
- facilitating aggregation and analysis of the cancer imaging datasets, allowing crossborder multi-centric cooperation on AI studies, including research and

- development of replicable AI algorithms for lung cancer screening and for strengthening the evidence base for AI uptake in lung cancer screening programmes;
- collection and assessment of benefits/harms data and other data on outcomes, quality assurance and cost-effectiveness relating to lung cancer screening programmes from the national level based on the established methods, infrastructure and networks within the previous EU4Health Programme funded projects;
- linking relevant experts and representatives from European medical societies and patient organisations to ensure broad outreach to corresponding national partner societies and patient organisations;
- effective dissemination as well as bidirectional knowledge exchange with all Member States and relevant candidate countries relating to lung cancer screening;
- close collaboration with related projects, such as those covering prostate and gastric cancer screening, and the Joint Action Implementation of cancer screening programmes ('EUCanScreen') from the 2023 EU4Health work programme action CR-g-23-38;
- close collaboration and alignment with the Commission's Joint Research Centre and the outputs of the planned Commission Initiative on Lung Cancer;
- exploration of the potential of artificial intelligence ('AI') in lung cancer screening in synergy with the activities under the European Cancer Imaging Initiative.

Specific action-level indicators for reporting purposes

- Number of Member States providing information on lung cancer screening pilot programmes or implementation studies
- Number of experts selected for the lung cancer screening network
- Number of Member States enrolled in lung cancer screening implementation studies within the project
- Number of citizens recruited for the implementation studies within the project

Expected impact (including EU added value, expected outputs and results)

- regularly updated reporting and gap analysis to guide Member States;
- enhanced knowledge on the current state of play and feasible and successful modalities of lung cancer screening programmes, including the integration of new AI-based screening technologies to improve detection and reduce disparities across Member States;
- further roll-out of lung cancer screening;
- further availability of lung cancer screening programmes across the Member States.

<u>Type of applicants targeted</u>: Public authorities, research organisation, civil society organisations, ERNs, academia and education establishments, hospitals, international organisations, networks in field of health

EU4H-2026-SANTE-PJ-03 - Call for proposals to pilot and implement cancer

screening programmes for prostate cancer (CR/CV&NCD-g-25-14)

Objectives (linked to general and specific objectives of the programme)

This action will contribute to the implementation of prostate cancer screening programmes, in a stepwise approach to ensure the gradual and appropriate planning, piloting, and roll-out of the screening programmes within national priorities, as called for in the 2022 Council Recommendation and upcoming European Guidelines on cancer screening. The use of AI in ongoing (pilot) programmes shall be assessed, and the potential use of AI, where feasible, further be explored. Synergies with actions implementing the European Cancer Imaging Initiative, in particular the Cancer Image Europe platform, shall be explored. Potential synergies with the project stemming out of the "Call for proposals on advancing the adoption of artificial intelligence in health" (DI-g-24-76 from 2024 EU4Health work programme) shall be explored.

Activities that can be funded (scope)

The action may include the following activities:

- facilitating implementation research via new pilots and programme rollout initiatives through:
 - monitoring and assessment of on-going implementation studies;
 - defining needs for and planning of new implementation studies based on gap analyses, building on deliverables of the PRAISE-U project;
 - o supporting, coordinating and running implementation studies within Member States;
 - o linking regional/national implementations studies within Member States to reduce duplication and human/financial resources as well as to increase study impact;
 - \circ $\;$ regular quality assessment and improvement of implementation research.
- facilitating aggregation and analysis of the prostate cancer imaging datasets, allowing cross-border multi-centric cooperation on AI studies, including research and development of replicable AI algorithms for prostate cancer screening and for strengthening the evidence base for AI uptake in prostate cancer screening programmes
- collection and assessment of benefits/harms data and other data on outcomes, quality assurance and cost-effectiveness relating to prostate cancer screening programmes from the national level based on the established methods, infrastructure and networks within the previous EU4Health Programme funded projects.
- linking relevant experts and representatives from European medical societies and patient organisations to ensure broad outreach to corresponding national partner societies and patient organisations.
- effective dissemination as well as bidirectional knowledge exchange with all Member States and relevant candidate countries relating to prostate cancer screening.
- close collaboration with related projects, such as those covering lung and gastric cancer screening, and the Joint Action Implementation of cancer screening programmes ('EUCanScreen') from the 2023 EU4Health work programme action CR-g-23-38.
- close collaboration with the Commission's Joint Research Centre, and the planned Commission Initiative on Prostate Cancer.

 exploration of the potential of artificial intelligence (AI) in prostate cancer screening to detect prostate cancer at an earlier stage and reduce disparities in access to diagnosis among high-risk populations in synergy with the activities under the European Cancer Imaging Initiative.

Specific action-level indicators for reporting purposes

- Number of Member States providing information on prostate cancer screening pilot programmes or implementation studies
- Number of experts selected for the prostate cancer screening network
- Number of Member States enrolled in prostate cancer screening implementation studies within the project
- Number of citizens recruited for the implementation studies within the project

Expected impact (including EU added value, expected outputs and results)

- regularly updated reporting and gap analysis to guide Member States;
- enhanced knowledge on the current state of play and feasible and successful modalities of prostate cancer screening programmes, including the integration of new AI-based screening technologies to improve detection and reduce disparities across Member States;
- further roll-out of prostate cancer screening;
- further availability of prostate cancer screening programmes across the Union based on European Guidelines, as available.

<u>Type of applicants targeted</u>: Public authorities, research organisation, civil society organisations, ERNs, academia and education establishments, hospitals, international organisations, networks in field of health

EU4H-2026-SANTE-PJ-04 - A European flagship initiative leveraging AI and health data for cardiovascular health and related non-communicable diseases: Advancing Risk Prediction, Prevention, Treatments, Personalised Care and Rehabilitation (CR/CV&NCD-g-25-16)

Objectives (linked to general and specific objectives of the programme)

This initiative aims to leverage AI and health data to accelerate the early detection, prediction, personalised prevention, integrated management and rehabilitation of CVDs and related NCDs, including rare and complex forms.

The initiative is structured around two complementary and mutually reinforcing objectives.

Together, they aim to lay the foundations for a European model of AI-enabled cardiovascular and comorbid chronic disease care, grounded in high-quality health data and real-world validated solutions.

The initiative should take into account the distinctive features of different population groups with regards to NCDs; such as socio-economic differences, gender differences etc.

Objective 1 — Leveraging Health Data for AI Applications in Cardiovascular and Related Chronic Diseases

The first objective is to structure, federate, and enable access to high-quality health data across the Union to support the development, training, validation, and deployment of AI tools focused on cardiovascular diseases and related non-communicable diseases (such as diabetes and obesity).

This will align with and prepare for the future application the EHDS, which provides the regulatory and technical framework to enable the secure, privacy preserving, and interoperable secondary use of health data across Member States.

Objective 2 — Deploying AI Solutions for Risk Prediction, Prevention, Treatments, and Personalised Care

The second objective is to identify, validate, and scale up mature AI applications capable of improving the risk prediction, early detection, personalised prevention, treatment, and rehabilitation of cardiovascular and related chronic diseases.

The action should also include AI models that integrate diverse health data sources—such as electronic health records, wearable devices, and socioeconomic and commercial determinants of health—to generate individualised risk assessments and care recommendations.

Activities that can be funded (scope)

To achieve the first objective, the initiative will support the following activities:

- Federating High-Quality and Diverse Health Datasets Across the EU: The
 action will support the identification, connection, and federation of large-scale
 datasets relevant to cardiovascular diseases and related chronic conditions.
 Particular attention will be paid to ensuring data quality, completeness,
 diversity, and representativeness, including the inclusion of data from
 underrepresented populations and healthcare contexts. This federation will enhance
 the ability to train robust, generalisable AI models across borders. The solutions
 proffered by the Collaborating Health Information European Framework ('CHIEF')
 initiative taken into account and implemented were appropriate.
- 2. Defining Minimum Technical Specifications for Cardiovascular Datasets: Building on existing Union and international standards, the initiative will support the definition of a core set of technical specifications for datasets to be used in AI development and validation. These specifications will include cardiovascular phenotypes, genomic and biometric markers, as well as metadata standards and labelling schemes. This will ensure consistency, comparability, and highquality input data for AI algorithms.
- 3. Supporting Targeted Data Collection Aligned with These Specifications: To address current gaps in data availability or standardisation, especially in some Member States or healthcare systems, the action will promote targeted efforts to collect or harmonise data in line with the agreed specifications. This includes support to public health institutions, research infrastructures, and data holders to strengthen data completeness and interoperability across the Union.
- 4. Establishing a Federated Data Infrastructure under the EHDS Framework: The initiative will support the development of a federated (distributed) repository model, leveraging the European Health Data Space. This infrastructure will enable secure, privacy-preserving and decentralised access to health datasets for the training, validation, benchmarking, and testing of AI models.

It will promote the **cross-border use of data without centralisation**, in full respect of Union rules on data protection, cybersecurity, and ethical use.

To achieve the second objective, the initiative will support the following activities:

- Develop a Strategic Roadmap for AI in Cardiovascular and Chronic Disease Care: to guide the safe, effective, and inclusive adoption of AI solutions. It will outline key milestones, enablers, stakeholder roles, and barriers across the innovation-to-adoption pathway. This roadmap should build on relevant Union initiatives, including JACARDI, the 1+ Million Genomes Initiative, and the European Virtual Human Twin Initiative.
- 2. **Map and Select Mature AI Solutions for Real-World Piloting**: The initiative will identify AI tools with strong evidence base and readiness for implementation/scale up, focusing on:
 - Early detection (e.g. imaging analysis, wearables, multimodal data),
 - Personalised risk prediction (e.g. EHRs, socioeconomic and commercial determinants),
 - Tailored prevention (e.g. individualised screening, lifestyle interventions, chronic disease management).
- 3. **Pilot AI Solutions in Real-World Healthcare Settings**: Selected AI tools will be piloted in diverse environments—such as hospitals, community clinics, general practice, telehealth platforms, and public health systems—across the Union. Particular attention will be paid to clinical integration, scalability, and inclusivity. Interdisciplinary collaboration involving clinicians, AI developers, engineers, patients, and regulators will be essential.
- 4. **Design a Blueprint and Deployment Protocols for Large-Scale Integration:**Based on lessons from the pilots, the initiative will develop a blueprint and a set of deployment protocols to guide the scale-up of validated solutions. These will address technical integration and interoperability, clinical validation and performance monitoring, regulatory alignment and organisational readiness, training, patient engagement, and data governance.
- 5. Produce Evidence-Based Guidelines and Organisational Recommendations: The initiative will support the development of:
 - Clinical guidelines for the safe and effective use of AI in cardiovascular and chronic disease care, including guidance on interpretation, validation, and data quality;
 - Operational guidance for healthcare institutions, to support adoption at the organisational level, including infrastructure, workflows, and governance.
- 6. Evaluate Impact and Foster Stakeholder Engagement: AI solutions will be assessed for feasibility, user acceptance, clinical effectiveness, cost-efficiency, and ethical compliance (equity, privacy, transparency). Broad stakeholder engagement will be promoted to ensure relevance, trust, and uptake.

For all listed activities, a particular spotlight should be on AI models that **support individual cardiovascular risk prediction, prevention and treatment**.

Specific action-level indicators for reporting purposes

 Number and diversity of health datasets made available for AI training or validation via the EHDS, covering multiple types of CVD-relevant data and populations across Member States.

- Number of AI tools piloted and deployed in real-world settings;
- Number of guidelines (clinical and organisational) developed;
- Number of member states and health institutions involved in piloting or implementation;
- Number of stakeholder engagement or dissemination activities conducted.

Expected impact (including EU added value, expected outputs and results)

This initiative is expected to generate **tangible**, **scalable results** supporting the adoption of **AI-driven personalised care** for cardiovascular diseases and related non-communicable conditions, while laying the **foundations of a trusted European data ecosystem** for health innovation.

Expected results - Data dimension

- Creation of a large-scale, federated, high-quality dataset for cardiovascular and metabolic diseases, aligned with the EHDS framework. This dataset will be representative, inclusive, and interoperable, and will enable the development, training and benchmarking of AI tools across borders.
- **Definition and uptake of minimum technical specifications** for cardiovascular datasets, including structured phenotypes, genetic and biometric markers, and metadata quality labelling.

Expected results - AI adoption dimension

- Validated AI solutions: A portfolio of AI tools will be piloted in real-world clinical settings, with demonstrated effectiveness in early detection, risk prediction, and personalised prevention of cardiovascular and related chronic diseases.
- **Deployment frameworks**: The initiative will produce practical guidelines and protocols to facilitate the integration and scale-up of AI applications across diverse healthcare systems. These will cover governance, interoperability, clinician training, patient engagement, and continuous performance monitoring.
- Strategic guidance: The publication of a roadmap and a blueprint for large-scale integration will inform health authorities, hospitals, and policymakers on how to responsibly and sustainably adopt AI tools, supporting informed decisions at national and Union levels.
- Robust evidence base: The project will generate comparative data on safety, performance (e.g. sensitivity, specificity, cost-effectiveness), usability and acceptability, informing both clinical practice and health policy. Anticipated impact
- Improved health outcomes: Earlier diagnosis and more targeted prevention of NCDs, leading to reduced disease progression, complications, and avoidable mortality.
- **Greater equity**: Enhanced access to personalised diagnostics and AI-supported care pathways, especially in underserved regions or Member States with limited innovation capacity.
- Efficiency and sustainability of health systems: Better use of resources through predictive and preventive approaches, reducing the burden of chronic conditions on healthcare infrastructures.
- Trust in European health AI: By ensuring compliance with data protection, safety, and transparency standards, the initiative will foster trust in the responsible use of AI for health in line with the AI Act and EHDS Regulation. It will also support the uptake and where relevant, the development of

specifications and standards foreseen under both frameworks, notably for interoperability, risk management and data governance.

Type of applicants targeted: Networks of experts such as European Reference Networks (ERNs), European societies or other recognised EU-level collaborations in cardiology and public health; Civil Society Organisations: Associations, Foundations and NGOs; Enterprises (incl. social enterprises and not for profit) in the field of public health; Private entities (for profit/not for profit); Public authorities, such as ministries of health, regional health agencies, or health insurance bodies actively engaged in public health initiatives.); Established networks in the field of public health, such as European or transnational organisations recognised under Union law.

EU4H-2026-SANTE-PJ-05 - Call for proposals on lifelong prevention for a healthy life with focus on cardiovascular diseases (CR/CV&NCD-g-25-18)

Objectives (linked to general and specific objectives of the programme)

The aim of this action is to contribute to reducing the burden of non-communicable diseases, including cancer, and their risk factors across the lifespan, supporting Member States' actions. The action targets:

- 1. lifelong prevention of non-communicable diseases, notably cardiovascular diseases and diabetes (targeting all age groups, with a particular focus on children and adolescents, and vulnerable groups);
- 2. active and healthy ageing, empowering older generations;
- 3. reducing the use and exposure to tobacco and related products, with a focus on young people's access to emerging tobacco and nicotine products;
- 4. reducing harmful alcohol consumption, in particular in young people and vulnerable groups;
- 5. the promotion of healthy diets and physical to improve health;
- 6. reducing the impact on mental wellbeing of social media and excessive screen time with a focus on children and young people.

Activities that can be funded (scope)

The activities will include:

- capacity-building for stakeholders to develop and pilot community-level, coordinated and innovative outreach and awareness actions to support the prevention of noncommunicable diseases and relevant risk factors (tobacco, alcohol, nutrition and physical activity, etc);
- activities to improve health literacy targeting vulnerable groups;
- development and piloting of tools and instruments to address the lifelong prevention of non-communicable diseases;
- development and piloting of innovative approaches to reduce the health risks associated with the use of tobacco and alcohol, in particular in vulnerable groups;
- · piloting of actions at community level on tackling risk factors for non-

communicable diseases, including unhealthy diets and physical inactivity;

• development and piloting of ambitious and innovative public health interventions on tackling risk factors such as tobacco, alcohol, and second-hand exposure to smoke and aerosols from traditional tobacco and emerging products.

This action is linked to and should support relevant actions by the Member States in the joint action (CR/CV&NCD-g-25-17) Lifelong prevention for a healthy life, including through screening – focus on cardiovascular diseases.

The activities should also include an equity dimension and aim at reducing health inequalities.

Supports priorities for action identified by Expert Group on Public Health and the EU4Health Steering Group (22nd May 2023). The Expert Group on Public Health identified priorities for action (2024-2026) that include health promotion and prevention of NCDs, cancer, mental health, and healthy longevity, lifelong prevention, vaccination and vaccine-preventable diseases and tackling infectious diseases.

Specific action-level indicators for reporting purposes

Piloting best and promising practices: Number of practices piloted from the EU Best Practice Portal; Number of innovative approaches developed/identified; Number of innovative approaches piloted.

Community level actions: Number of community level actions identified and/or developed; Number of community level actions implemented.

Awareness campaigns: Number of awareness campaigns developed per vulnerable group of the population.

Capacity building: Number of participants attending the capacity-building events; Number of entities per type participating; Number of trainees declaring to have introduced changes in their activity after the course.

Expected impact (including EU added value, expected outputs and results)

This action will implement projects on health promotion, lifelong prevention of NCDs, including cancer, and aim for healthy diets, physical activity, and healthy and active ageing. It will also build on the priorities set by the Expert Group on Public Health in the area of prevention.

This action is expected to result in the piloting of population-level interventions, awareness raising campaigns, capacity-building activities, and support for patient groups and organisations representing vulnerable groups.

This action is expected to support the efforts of Member States in addressing the challenges of an ageing population by strengthening lifelong prevention of NCDs, including cancer and cardiovascular diseases.

The short-term impact will be an increased number of public health interventions being scaled up in Member States, improvements in health promotion, prevention of NCDs, including cancer and their risk factors.

<u>Type of applicants targeted</u>: Academia and education establishments, research institutes, hospitals, expert networks including ERNs; Civil Society Organisations: Associations, Foundations, NGOs

EU4H-2026-SANTE-PJ-06 - Call for proposals to support the development of a medicine pricing, reimbursement and access tracker through the EURIPID database (HS-g-25-20)

<u>Objectives (linked to general and specific objectives of the programme)</u>

The objectives are to:

- measure and increase understanding of patient access to medicines in the Union;
- increase the quality of the database, in terms of timely/correct data delivery;
- expand the scope of the EURIPID members (to all the Member States) and data;
- leverage usefulness of the data beyond external reference pricing purposes.

Activities that can be funded (scope)

The scope of this action is to develop through the EURIPID database:

- a "pricing and reimbursement ('P&R') tracker", including national information on early access schemes; P&R applications, status, decision; and P&R criteria or conditions (general and product-specific);
- access dashboards, building on OECD indicators, including on availability (e.g., coverage status, time-to-reimbursement), affordability (e.g., cost of treatment), accessibility (e.g., consumption/uptake);
- an annual trend analysis report of access to medicines in the Union;
- solutions that can facilitate data sharing with EURIPID, such as automatization using application programming interface and machine-machine interaction with each Member State;
- reinforced interoperability of EURIPID with other existing databases (e.g. the European Shortages Medicine Platform, Substance, Product, Organisation and Referential master data, Product Management Service, etc.) and integrating data assets in the European Health Data Space.

Specific action-level indicators for reporting purposes

- Number of Member States providing data to the P&R Tracker
- Number of Member States connected via automated data exchange (API/machine-to-machine interaction) with EURIPID
- Number of trend analysis reports published
- Number of references to the annual trend analysis report in national or EU-level policy documents
- Number of project leaflets, factsheets, user guides, and other communication materials produced and disseminated
- Number of webinars, workshops, and other dissemination activities organised
- Number of participants attending webinars, workshops, and dissemination activities
- Satisfaction rate of participants in webinars, workshops, and dissemination activities (based on post-event surveys)

- Number of interoperability links established between EURIPID and other EU databases (e.g., SPOR, PMS, shortages platform)
- Number of countries declaring that EURIPID has impacted their national pricing and reimbursement system of medicines

Expected impact (including EU added value, expected outputs and results)

In the short term, this action will provide EURIPID members with a better overview of access, P&R measures and decisions across the Member States.

In the longer term, it is expected to support mutual learning between national authorities and help the Member States in taking better pricing and reimbursement decisions, with a view to improve access, availability, and affordability of medicines. This is in line with the recommendations in the Draghi Report on the future of European competitiveness, and with the priority to ensure supply of affordable medicines, as outlined in the mission letter from Commission President von der Leyen to the Commissioner for Health and Animal Welfare.

The proposed "pricing and reimbursement ('P&R') tracker" and access dashboard will allow improved monitoring of patients' access to medicines across the Union, including for cancer treatments. Having this data available prior to the application of the proposed pharmaceutical reform, will serve to measure the baseline and subsequently the impact of the proposed measures that aim to increase access to medicines across the Union, including for cancer treatments.

This action builds on action HS-g-22-17.01 of the 2022 EU4Health work programme²⁵, Call for proposals to develop early warning features and guidance in the area of pricing through the EURIPID database, based on competition cases, therefore it is crucial that it is launched timely to ensure continuation of EURIPID functioning.

<u>Type of applicants targeted</u>: Authorities competent in the domain of pricing and reimbursement of medicines from the Member States being members of EURIPID

EU4H-2026-SANTE-PJ-07 - Call for proposals for a programme on orphan medical devices, in particular targeting paediatric patients (HS-g-25-24)

Objectives (linked to general and specific objectives of the programme)

This action aims to support innovation in the field of medical devices by supporting non-profit organisations or consortia that provide a platform for academic bodies, scientific societies, developers of devices, in particular SMEs, and NGOs with a specific interest in innovative medical devices to help foster and guide the development of orphan devices, in particular in areas of unmet medical needs and paediatric patients. It takes inspiration from the Paediatric Device Consortia Grants Program of the US Food and Drugs Administration ('FDA') and builds on the positive experience gained with action HS-g-23-65 call for proposals for a programme on orphan medical devices in particular targeting paediatric patients, launched under the 2023 EU4Health work programme²⁶.

²⁵ 2022 EU4Health Work Programme

²⁶ 2023 EU4Health Work Programme

Activities that can be funded (scope)

A wide range of activities can be funded that support, among other things, the development, design, production and distribution or orphan devices, including intellectual property advising, prototyping, engineering, laboratory and animal testing, grant-writing, and clinical investigation design.

The eligible entities should facilitate the development, production, and distribution of orphan devices, in particular for paediatric patients by:

- mapping unmet medical needs that could be addressed by orphan devices;
- encouraging innovation and connecting relevant players (e.g., academia, scientific societies, users) with orphan device ideas with potential manufacturers;
- mentoring and managing orphan device projects through the development process, including product identification, prototype design, device development, and marketing;
- connecting developers of innovative devices and physicians to existing financing resources;
- · assessing the scientific and medical merit of proposed orphan device projects;
- gathering and evaluating pre-clinical data to support the safety and/or performance of the orphan device;
- providing assistance and advice as needed on business development, personnel training, prototype development, intellectual property protection and postmarketing needs;
- advising about regulatory requirements to device developers in support of achieving CE marking for the orphan devices; and
- supporting the demonstration of conformity with the relevant requirements laid down in Regulation (EU) 2017/745 or Regulation (EU) 2017/746 with a view to allowing the CE marking of the product building on the guidance MDCG 2024-10 including the scientific advice procedure from the expert panels on medical devices²⁷.

Specific action-level indicators for reporting purposes

- number of orphan devices supported
- number of paediatric devices supported
- number of prototypes developed
- number of business plans drafted
- number of clinical data collection and/evaluation projects launched
- number of clinical data collection and/evaluation projects supported
- number of EU conformity certificates obtained.

Expected impact (including EU added value, expected outputs and results)

This action is intended to promote the development of innovative orphan devices especially for paediatric patients, with a particular focus on devices responding to unmet medical needs.

²⁷ See EMA pilot programme to support orphan medical devices New pilot programme to support orphan medical devices | European Medicines Agency (EMA).

<u>Type of applicants targeted</u>: Academia and education establishments, research institutes, hospitals, expert networks including ERNs; civil society organisations: associations, foundations, NGOs, enterprises (including social enterprises and not for profit) in the field of public health, private entities (for profit, not for profit).

EU4H-2026-SANTE-PJ-08 - Call for proposals for health data for biotech innovation leveraging the European Health Data Space (DI-g-25-31)

Objectives (linked to general and specific objectives of the programme)

The general objective of this action is to accelerate the development and deployment of AI and digital solutions in the biotech sector driven by health data, ensuring its secure and responsible use through the EHDS and leveraging AI Factories to augment these efforts.

Objectives:

- Create a multistakeholder platform that brings together the biotech industry, data holders, healthcare providers, patient organisations, regulatory bodies and AI Factories to exchange best practices on data access, AI applications, and innovation acceleration, facilitating collaboration, knowledgesharing, and innovation in the biotechnology sector.
- Identify and prioritise the most promising digital / AI applications for the biotechnology sector, based on criteria such as potential impact on health outcomes, feasibility, technological maturity, and alignment with sectoral needs. Potentially, while also leveraging AI Factory resources for enhancement and validation, rapid prototyping and testing of AI-driven biotech solutions, enhancing the speed and efficiency of bringing innovations from concept to healthcare implementation.
- Analyse the challenges and barriers to the development and deployment of digital / AI solutions in the biotechnology sector, including data quality and availability, regulatory frameworks, ethical and privacy concerns, intellectual property ownership, technical barriers, and scientific validation, and identify potential solutions or strategies to address these challenges, guiding the effective utilization of the EHDS.
 - Develop concrete recommendations to support the coordinated development of the EHDS for digital / AI solutions in the biotechnology sector, including for policymakers, industry leaders, and researchers, with a focus on fostering innovation, improving health outcomes, and enhancing the competitiveness of the Union's biotechnology sector.

This action aims to bring together biotech sector industry, developers of AI solutions, Member States' authorities active in the area of secondary use of health data and Research infrastructures.

Activities that can be funded (scope)

• Establish a multistakeholder platform/community of practice: create a platform that brings together biotech industry, research institutions, healthcare providers, patient organisations, and regulatory bodies and AI Factories to facilitate collaboration, knowledge-sharing among stakeholders, and the discussion of challenges in the use of AI in the biotechnology sector.

- Conduct a landscape analysis: map the current state of leveraging health data for AI in the biotech sector and identify the most relevant health datasets for the biotech sector, based on criteria such as potential impact on health outcomes, feasibility, and alignment with sectoral needs. Building on existing projects. Potentially incorporate also the AI Factories in this landscape analysis to also explore further application potential.
- Develop a strategic roadmap: create a roadmap for the development, deployment, and scale-up of effective AI solutions in the biotech sector, including recommendations for policy-makers, industry leaders, and researchers. Promote the adoption of standardized data formats and frameworks that facilitate the role data and research infrastructure relevant to the biotech sector, taking into account AI Factory capabilities and building on existing projects and activities in this area.
- Pilot the roles for health data infrastructures under the EHDS frameworks: This activity involves analysing and piloting the roles, and the potential federation of, specific health data infrastructures (genomic, cancer imaging, and brain) within the EHDS frameworks, as well as access to computing resources, and other related data and support services, to support AI-driven biotech innovations. The analysis shall examine the current state of these infrastructures, identify gaps and limitations, and pilot their integration with the EHDS frameworks to enable seamless data sharing and access. The goal is to demonstrate the value of these infrastructures in supporting AI applications in the biotech sector and provide recommendations for integration of such infrastructures into the EHDS frameworks.
- **Develop case studies**: create case studies of successful AI applications in the biotech sector, and share them with stakeholders to promote best practices, pathways and knowledge-sharing, these case studies should focus on explainable AI.
- **Integrate AI Factory Expertise:** Incorporate AI Factory technological advancements in collaboration with the use of the EHDS infrastructure, for simulations and analytics to refine and optimise biotech AI solutions, ensuring alignment with healthcare needs.
- **Monitor and evaluate progress**: pilot a methodology and_tools to monitor and evaluate progress towards the strategic roadmap objectives, to provide insights and adjustments needed for continuous improvement.

The action should leverage existing initiatives like the 1+ Million Genomes and data infrastructures proving access to health data relevant for the biotech industry.

Specific action-level indicators for reporting purposes

- Number and diversity of actors (biotech industry, research institutes, AI developers, health institutions, patient organisations, Member states authorities) participating in the biotech multi-stakeholders platform;
- Number and significance of AI applications/Language Models for the biotech sector designed piloted and deployed in real-world framework;
- Number and diversity of health data infrastructures available for AI training for biotech applications, under the EHDS framework, covering multiple types of data and populations across Member States;
- Number of case studies of successful AI applications/Language Models relevant for biotech:

Expected impact (including EU added value, expected outputs and results)

- Increased collaboration and knowledge-sharing: establish an active network of stakeholders, encouraging collaboration and knowledge-sharing among biotech and healthcare sectors.
- Accelerate innovation in the Union's biotech industry: support the
 development and deployment of effective digital / AI solutions in the biotech
 sector, driving innovation and competitiveness of the Union's biotech industry,
 including through AI Factory enabled advancements.
- **Enhanced health outcomes:** facilitate the broader adoption of digital / AI solutions in the biotechnology sector enhancing patient care, diagnosis accuracy and treatment efficiency across the Union.
- **Regulatory clarity:** clarify regulatory requirements and standards/specifications for AI development and deployment relevant to the biotech sector and provide pathways for biotech stakeholders and for health data and research infrastructures integration into the EHDS frameworks.
- <u>Type of applicants targeted</u>: biotech sector industry, developers of AI solutions, Member States' authorities active in the area of secondary use of health data from at least 3 Member States, Research and health data infrastructures with experience in development and validation of AI solutions.

EU4H-2026-SANTE-PJ-09 - Call for proposals to contribute to the organisation of conferences (OA-g-25-33)

Objectives (linked to general and specific objectives of the programme)

The objective of this action is to support the organisation of not-for-profit, Union-wide high-level science-policy-society conferences that bring together all interested parties such as citizens, patients, practitioners, scientists, policy makers from local, regional, and Union level. The conferences will cover important health topics that are related to the Union's health priorities, and thereby contribute to the development and implementation of the European Health Union.

The Commission considers that proposals requesting an EU contribution of EUR 200 000 would allow this specific challenge to be addressed appropriately.

These conferences are an opportunity for discussion on how to work better together at Union level on one or more health-related topics and will allow Member States, third countries associated to the EU4Health Programme and relevant stakeholders to exchange information and good practices on relevant topics in the field of public health.

Grants may be awarded to support the organisation of conferences that correspond to the objectives and the priorities of the EU4Health Programme, and which have a Union-wide dimension.

Activities that can be funded (scope)

The proposal should cover several Commission priorities addressed by the 2025 EU4Health annual work programme.

Applicants are encouraged to address several of the priorities listed below, as proposals that span multiple or all areas will be considered more relevant:

- Cancer, cardiovascular and other non-communicable diseases
- Health systems and workforce including in relation to demographic changes;
- Health promotion and disease prevention, mental health & social media
- One health approach;
- Health security;
- Pharmaceuticals and medical devices; Biotechnology;
- Digital transition across health challenges;
- Global health.

Conferences organised by the Presidencies of the European Union fall outside the scope of the present call.

The activities included in the proposals should address as many as possible of the following aspects:

- undertake an effective mobilisation of a broad and diverse audience with participation of policymakers (EU, national, regional and where necessary global levels), academia, industry, civil society (including patients' organisations and other relevant representatives) and an expected significant reach (i.e., at least 500 in-person participants and demonstrated by previous similar experience (e.g. in conference reports).
- provide a platform to explain and debate EU health initiatives and health societal challenges;
- provide a dedicated physical area (e.g. a stand) for DG SANTE to present health priorities;
- include sustainable outreach activities before, during and post event with multiplier effect including on social media;
- facilitate high-level policy dialogues attracting relevant health actors from different key sectors including at least one high-level session dedicated to DG SANTE priorities;
- the use of innovative approaches in running the event are a plus.

Applicants are advised to address as many of the above aspects as possible, as proposals that encompass a broad range of these elements will be deemed more relevant.

Specific action-level indicators for reporting purposes

- Number of Commission priorities included in the 2025 EU4Health annual work programme addressed by the conference
- Total number of participants (disaggregated by in-person and online participation)

- Number of participants by sector, organisation and type of audience (director, expert, trainee, etc.), Member State, and level of responsibility of the participant
- The duration of the social media dissemination before, during and post event

Expected impact (including EU added value, expected outputs and results)

This action will involve public or private entities with expertise on organising conferences in public health domain topics.

Applicants must clearly describe the expected number and profile/function of target participants in the conference, including their distribution by Member States or third countries associated to the EU4Health Programme, organisation, and type of expertise.

The conferences should include high level speakers, and a representative number of participants from all relevant fields of the challenges to be discussed.

The action will support communication activities addressed to the general public and/or to specific groups of people or health professionals, in order to promote the European Health Union and its different initiatives.

Conferences must have a Union-wide dimension. The conferences will not focus on a specific condition or disease however, they will focus on current cross-cutting Union policy issues.

<u>Type of applicants targeted</u>: Public or private non-profit entities with expertise in organising events in the public health domain.

3. Available budget

The estimated available call budget is **EUR 56 816 810**.

Specific budget information per topic can be found in the table below:

Topic	Topic budget
EU4H-2026-SANTE-PJ-01 - Call for proposals to pilot and implement cancer screening programmes for gastric cancer	€ 3,000,000
EU4H-2026-SANTE-PJ-02 - Call for proposals to pilot and implement cancer screening programmes for lung cancer (CR/CV&NCD -g-25-13)	€ 7,440,000
EU4H-2026-SANTE-PJ-03 - Call for proposals to pilot and implement cancer screening programmes for prostate cancer (CR/CV&NCD-g-25-14)	€ 7,440,000
EU4H-2026-SANTE-PJ-04 - A European flagship initiative leveraging AI and health data for cardiovascular health and related non-communicable diseases: Advancing Risk Prediction, Prevention, Treatments, Personalised Care and Rehabilitation (CR/CV&NCD-g-25-16)	€ 20,000,000
EU4H-2026-SANTE-PJ-05 - Call for proposals on lifelong prevention for a healthy life with focus on cardiovascular diseases (CR/CV&NCD-g-25-18)	€ 2,000,000

EU4H-2026-SANTE-PJ-06 - Call for proposals to support the development of a medicine pricing, reimbursement and access tracker through the EURIPID database (HS-g-25-20)	€ 750,000
EU4H-2026-SANTE-PJ-07 - Call for proposals for a programme on orphan medical devices, in particular targeting paediatric patients (HS-g-25-24)	€ 1,200,000
EU4H-2026-SANTE-PJ-08 - Call for proposals for health data for biotech innovation leveraging the European Health Data Space (DI-g-25-31)	€ 14,386,810
EU4H-2026-SANTE-PJ-09 - Call for proposals to contribute to the organisation of conferences (OA-g-25-33)	€ 600,000

We expect to sign around 13 grant agreements, distributed per topic as follows:

Topic	Expected number of grant agreements to be signed
EU4H-2026-SANTE-PJ-01 - Call for proposals to pilot and implement cancer screening programmes for gastric cancer (CR/CV&NCD -g-25-12)	1
EU4H-2026-SANTE-PJ-02 - Call for proposals to pilot and implement cancer screening programmes for lung cancer (CR/CV&NCD -g-25-13)	1
EU4H-2026-SANTE-PJ-03 - Call for proposals to pilot and implement cancer screening programmes for prostate cancer (CR/CV&NCD-g-25-14)	1
EU4H-2026-SANTE-PJ-04 - A European flagship initiative leveraging AI and health data for cardiovascular health and related non-communicable diseases: Advancing Risk Prediction, Prevention, Treatments, Personalised Care and Rehabilitation (CR/CV&NCD-g-25-16)	1
EU4H-2026-SANTE-PJ-05 - Call for proposals on lifelong prevention for a healthy life with focus on cardiovascular diseases (CR/CV&NCD-g-25-18)	1
EU4H-2026-SANTE-PJ-06 - Call for proposals to support the development of a medicine pricing, reimbursement and access tracker through the EURIPID database (HS-g-25-20)	1
EU4H-2026-SANTE-PJ-07 - Call for proposals for a programme on orphan medical devices, in particular targeting paediatric patients (HS-g-25-24)	3
EU4H-2026-SANTE-PJ-08 - Call for proposals for health data for biotech innovation leveraging the European Health Data Space (DI-g-25-31)	1

EU4H-2026-SANTE-PJ-09 - Call for proposals to contribute to the organisation of conferences (OA-g-25-33)	3

We reserve the right not to award all available funds or to redistribute them between the call priorities, depending on the proposals received and the results of the evaluation.

4. Timetable and deadlines

Timetable and deadlines (indicative)	netable and deadlines (indicative)	
Call opening:	23 September 2025	
Deadline for submission:	06 January 2026 – 17:00:00 CET (Brussels)	
Evaluation:	January – March 2026	
Information on evaluation results:	April – May 2026	
GA signature:	September – October 2026	

5. Admissibility and documents

Proposals must be submitted before the **call deadline** (see timetable section 4).

Proposals must be submitted **electronically** via the Funding & Tenders Portal Electronic Submission System (accessible via the Topic page in the <u>Calls for proposals</u> section). Paper submissions are NOT possible.

Proposals (including annexes and supporting documents) must be submitted using the forms provided *inside* the Submission System ($^{\triangle}$ NOT the documents available on the Topic page — they are only for information).

Proposals must be **complete** and contain all the requested information and all required annexes and supporting documents:

- Application Form Part A contains administrative information about the participants (future coordinator, beneficiaries and affiliated entities) and the summarised budget for the project (to be filled in directly online)
- Application Form Part B contains the technical description of the project (template to be downloaded from the Portal Submission System, completed, assembled and re-uploaded)

- mandatory annexes and supporting documents (templates to be downloaded from the Portal Submission System, completed, assembled and reuploaded):
 - detailed budget table/calculator
 - CVs (standard) of core project team
 - activity reports of last year: not applicable
 - list of previous projects (key projects for the last 4 years) (template available in Part B)
 - other mandatory annexes:

for topic EU4H-2026-SANTE-PJ-09 - Call for proposals to contribute to the organisation of conferences (OA-g-25-33)

- Summary report of the previous conferences
- Draft programme of the conference to be held including of the draft high-level session dedicated to DG SANTE priorities

Please note that the amounts entered into the summarised budget table (filled in directly online) must correspond to the amounts calculated in the detailed budget table. In case of discrepancies, the amounts in the online summarised budget table will prevail.

At proposal submission, you will have to confirm that you have the **mandate to act** for all applicants. Moreover, you will have to confirm that the information in the application is correct and complete and that all participants comply with the conditions for receiving EU funding (especially eligibility, financial and operational capacity, exclusion, etc). Before signing the grant, each beneficiary and affiliated entity will have to confirm this again by signing a declaration of honour (DoH). Proposals without full support will be rejected.

Your application must be **readable**, **accessible and printable** (please check carefully the layout of the documents uploaded).

Proposals are limited to maximum **70 pages** (Part B). Evaluators will not consider any additional pages.

You may be asked at a later stage for further documents (for legal entity validation, financial capacity check, bank account validation, etc).

For more information about the submission process (including IT aspects), consult the Online Manual.

6. Eligibility

Eligible participants (eligible countries)

In order to be eligible, the applicants (beneficiaries and affiliated entities) must:

- be legal entities (public or private bodies)
- be established in one of the eligible countries, i.e.:
 - EU Member States (including overseas countries and territories (OCTs))
 - eligible non-EU countries:

 listed EEA countries and countries associated to the EU4Health Programme (list of participating countries)

Beneficiaries and affiliated entities must register in the <u>Participant Register</u> — before submitting the proposal — and will have to be validated by the Central Validation Service (REA Validation). For the validation, they will be requested to upload documents showing legal status and origin.

Other entities may participate in other consortium roles, such as associated partners, subcontractors, third parties giving in-kind contributions, etc (see section 13).

For the participation of associated partners, the rules on eligible countries apply as laid down in the present section, subsection 'eligible participants' of this call.

Specific cases and definitions

Natural persons — Natural persons are NOT eligible (with the exception of self-employed persons, i.e. sole traders, where the company does not have legal personality separate from that of the natural person).

International organisations — International organisations are eligible. The rules on eligible countries do not apply to them.

Entities without legal personality — Entities which do not have legal personality under their national law may exceptionally participate, provided that their representatives have the capacity to undertake legal obligations on their behalf, and offer guarantees for the protection of the EU financial interests equivalent to that offered by legal persons²⁸.

EU bodies — EU bodies (with the exception of the European Commission Joint Research Centre) can NOT be part of the consortium.

Associations and interest groupings — Entities composed of members may participate as 'sole beneficiaries' or 'beneficiaries without legal personality'²⁹. A Please note that if the action will be implemented by the members, they should also participate (either as beneficiaries or as affiliated entities, otherwise their costs will NOT be eligible).

European Reference Networks (ERNs) — These cover networks between healthcare providers and centres of expertise in the Member States to reinforce healthcare cooperation, in particular in the area of rare diseases, in line with the objectives set out in Article 12 of Directive 2011/24.

Countries currently negotiating association agreements — Beneficiaries from countries with ongoing negotiations for participation in the programme (see list of participating countries above) may participate in the call and can sign grants if the negotiations are concluded before grant signature and if the association covers the call (i.e. is retroactive and covers both the part of the programme and the year when the call was launched).

EU restrictive measures — Special rules apply for entities subject to $\underline{\text{EU restrictive}}$ measures under Article 29 of the Treaty on the European Union (TEU) and Article 215 of the Treaty on the Functioning of the EU (TFEU)³⁰. Such entities are not eligible to

²⁸ See Article 200(2)(c) EU Financial Regulation 2024/2509.

For the definitions, see Articles 190(2) and 200(2)(c) EU Financial Regulation 2024/2509.

Please note that the EU Official Journal contains the official list and, in case of conflict, its content prevails over that of the EU Sanctions Map.

participate in any capacity, including as beneficiaries, affiliated entities, associated partners, subcontractors or recipients of financial support to third parties (if any).

EU conditionality measures — Special rules apply for entities subject to measures adopted on the basis of EU Regulation 2020/2092³¹. Such entities are not eligible to participate in any funded role (beneficiaries, affiliated entities, subcontractors, recipients of financial support to third parties, etc). Currently such measures are in place for Hungarian public interest trusts established under the Hungarian Act IX of 2021 or any entity they maintain (see Council Implementing Decision (EU) 2022/2506, as of 16 December 2022).

For more information, see <u>Rules for Legal Entity Validation, LEAR Appointment and Financial Capacity Assessment</u>.

Consortium composition

Topic Consortium composition conditions EU4H-2026-SANTE-PJ-01 - Call for proposals to pilot and Proposals must be submitted by a consortium of at least 3 beneficiaries from 3 different implement cancer screening programmes for gastric cancer eligible countries. EU4H-2026-SANTE-PJ-02 - Call for proposals to pilot and Proposals must be submitted by a consortium implement cancer screening programmes for lung cancer of at least 5 beneficiaries from 5 different (CR/CV&NCD -g-25-13) eligible countries. EU4H-2026-SANTE-PJ-03 - Call for proposals to pilot and Proposals must be submitted by a consortium of at least 5 beneficiaries from 5 different implement cancer screening programmes for prostate cancer (CR/CV&NCD-g-25-14) eligible countries. EU4H-2026-SANTE-PJ-04 - A European flagship initiative Proposals must be submitted by a consortium leveraging AI and health data for cardiovascular health and of at least 5 beneficiaries from 5 different related non-communicable diseases: Advancing Risk eligible countries. Prediction, Prevention, Treatments, Personalised Care and Rehabilitation (CR/CV&NCD-g-25-16) EU4H-2026-SANTE-PJ-05 - Call for proposals on lifelong Proposals must be submitted by a consortium of at least 5 beneficiaries from 5 different prevention for a healthy life with focus on cardiovascular diseases (CR/CV&NCD-g-25-18) eligible countries. Proposals must be submitted by a consortium which complies with the following conditions: EU4H-2026-SANTE-PJ-06 - Call for proposals to support the - at least 4 beneficiaries from 3 different development of a medicine pricing, reimbursement and eligible countries. access tracker through the EURIPID database (HS-q-25-20) - applicants should be **EURIPID members**, public authorities on pricing reimbursement of medicines

Regulation (EU, Euratom) 2020/2092 of the European Parliament and of the Council of 16 December 2020 on a general regime of conditionality for the protection of the Union budget (OJ L 325, 20.12.2022, p. 94).

EU4H-2026-SANTE-PJ-07 - Call for proposals for a programme on orphan medical devices, in particular targeting paediatric patients (HS-g-25-24)	Proposals may be submitted either by a single applicant or by_a consortium (no minimum requirement).
EU4H-2026-SANTE-PJ-08 - Call for proposals for health data for biotech innovation leveraging the European Health Data Space (DI-g-25-31)	Proposals must be submitted by a consortium of at least 5 beneficiaries from 5 different eligible countries.
EU4H-2026-SANTE-PJ-09 - Call for proposals to contribute to the organisation of conferences (OA-g-25-33)	Proposals may be submitted either by a single applicant or by a consortium (no minimum requirement).

Eligible activities

Applications will only be considered eligible if their content corresponds wholly (or at least in part) to the topic description for which they are submitted.

Eligible activities are the ones set out in section 2 above.

The following activities are not considered as eligible for funding under this call:

- For topic EU4H-2026-SANTE-PJ-05 Call for proposals on lifelong prevention for a healthy life with focus on cardiovascular diseases (CR/CV&NCD-g-25-18) -
 - Development or purchase of healthcare related products.

Projects must comply with EU policy interests and priorities (such as environment, social, security, industrial and trade policy, etc). Projects must also respect EU values and European Commission policy regarding reputational matters (e.g. activities involving capacity building, policy support, awareness raising, communication, dissemination, etc)³².

Financial support to third parties is not allowed for the following topics:

- EU4H-2026-SANTE-PJ-01 Call for proposals to pilot and implement cancer screening programmes for gastric cancer (CR/CV&NCD-g-25-12)
- EU4H-2026-SANTE-PJ-02 Call for proposals to pilot and implement cancer screening programmes for lung cancer (CR/CV&NCD -g-25-13)
- EU4H-2026-SANTE-PJ-03 Call for proposals to pilot and implement cancer screening programmes for prostate cancer (CR/CV&NCD-g-25-14)
- EU4H-2026-SANTE-PJ-05 Call for proposals on lifelong prevention for a healthy life with focus on cardiovascular diseases (CR/CV&NCD-g-25-18)
- EU4H-2026-SANTE-PJ-06 Call for proposals to support the development of a medicine pricing, reimbursement and access tracker through the EURIPID database (HS-g-25-20)

See, for instance, <u>Guidance on funding for activities related to the development, implementation, monitoring and enforcement of Union legislation and policy.</u>

- EU4H-2026-SANTE-PJ-07 Call for proposals for a programme on orphan medical devices, in particular targeting paediatric patients (HSg-25-24)
- EU4H-2026-SANTE-PJ-09 Call for proposals to contribute to the organisation of conferences (OA-g-25-33)

For the topics:

- EU4H-2026-SANTE-PJ-04 A European flagship initiative leveraging AI and health data for cardiovascular health and related noncommunicable diseases: Advancing Risk Prediction, Prevention, Treatments, Personalised Care and Rehabilitation (CR/CV&NCD-g-25-16)
- EU4H-2026-SANTE-PJ-08 Call for proposals for health data for biotech innovation leveraging the European Health Data Space (DI-g-25-31)

Financial support to third parties is allowed for grants or similar forms of support under the following conditions³³:

- the calls must be open, published widely and conform to EU standards concerning transparency, equal treatment, conflict of interest and confidentiality
- the calls must remain open for at least two months
- the outcome of the call must be published on the participants' websites, including a description of the selected projects, award dates, project durations, and final recipient legal names and countries
- the calls must have a clear European dimension.

Your project application must clearly specify why financial support to third parties is needed, how it will be managed and provide a list of the different types of activities for which a third party may receive financial support. The proposal must also clearly describe the results to be obtained.

Geographic location (target countries)

Proposals must relate to activities taking place in the eligible countries (see above).

Duration

Topic Project duratio		
EU4H-2026-SANTE-PJ-01 - Call for proposals to pilot and implement cancer screening programmes for gastric cancer	Projects should normally be maximum 36 months.	
	Projects should normally be maximum 36 months.	

³³ As per Article 207 of the FR, the maximum amount of financial support that can be paid to a third party which shall not exceed EUR 60 000 and the criteria for determining the exact amount.

EU4H-2026-SANTE-PJ-02 - Call for proposals to pilot and implement cancer screening programmes for lung cancer (CR/CV&NCD -g-25-13)		
EU4H-2026-SANTE-PJ-03 - Call for proposals to pilot and implement cancer screening programmes for prostate cancer (CR/CV&NCD-g-25-14)	Projects should normally be maximum 36 months.	
EU4H-2026-SANTE-PJ-04 - A European flagship initiative leveraging AI and health data for cardiovascular health and related non-communicable diseases: Advancing Risk Prediction, Prevention, Treatments, Personalised Care and Rehabilitation (CR/CV&NCD-g-25-16)	Projects should range between 24 and 36 months.	
EU4H-2026-SANTE-PJ-05 - Call for proposals on lifelong prevention for a healthy life with focus on cardiovascular diseases (CR/CV&NCD-g-25-18)	Projects should normally be maximum 36 months.	
EU4H-2026-SANTE-PJ-06 - Call for proposals to support the development of a medicine pricing, reimbursement and access tracker through the EURIPID database (HS-g-25-20)	Projects should range between 24 and 36 months.	
EU4H-2026-SANTE-PJ-07 - Call for proposals for a programme on orphan medical devices, in particular targeting paediatric patients (HS-g-25-24)	Projects should normally be maximum 36 months.	
EU4H-2026-SANTE-PJ-08 - Call for proposals for health data for biotech innovation leveraging the European Health Data Space (DI-g-25-31)	Projects should range between 24 and 36 months.	
EU4H-2026-SANTE-PJ-09 - Call for proposals to contribute to the organisation of conferences (OA-g-25-33)	Projects should normally be maximum 12 months. The duration of the conference is up to 5 calendar days.	

Extensions are possible, if duly justified and through an amendment.

Project budget

Project budgets (requested grant amount) are expected to be around:

Topic	Indicative project budget	
EU4H-2026-SANTE-PJ-01 - Call for proposals to pilot and implement cancer screening programmes for gastric cancer	€ 3,000,000	
EU4H-2026-SANTE-PJ-02 - Call for proposals to pilot and implement cancer screening programmes for lung cancer (CR/CV&NCD -g-25-13)	€ 7,440,000	
EU4H-2026-SANTE-PJ-03 - Call for proposals to pilot and implement cancer screening programmes for prostate cancer (CR/CV&NCD-g-25-14)	€ 7,440,000	
EU4H-2026-SANTE-PJ-04 - A European flagship initiative leveraging AI and health data for cardiovascular health and related non-communicable diseases: Advancing Risk Prediction, Prevention, Treatments, Personalised Care and Rehabilitation (CR/CV&NCD-g-25-16)	€ 20,000,000	

EU4H-2026-SANTE-PJ-05 - Call for proposals on lifelong prevention for a healthy life with focus on cardiovascular diseases (CR/CV&NCD-g-25-18)	€ 2,000,000
EU4H-2026-SANTE-PJ-06 - Call for proposals to support the development of a medicine pricing, reimbursement and access tracker through the EURIPID database (HS-g-25-20)	€ 750,000
EU4H-2026-SANTE-PJ-07 - Call for proposals for a programme on orphan medical devices, in particular targeting paediatric patients (HS-g-25-24)	€ 300,000 - €400,000
EU4H-2026-SANTE-PJ-08 - Call for proposals for health data for biotech innovation leveraging the European Health Data Space (DI-g-25-31)	€ 14,386,810
EU4H-2026-SANTE-PJ-09 - Call for proposals to contribute to the organisation of conferences (OA-g-25-33)	€ 200,000

The grant awarded may be lower than the amount requested.

Ethics

Projects must comply with:

- highest ethical standards and
- applicable EU, international and national law (including Directive <u>2005/28</u> on investigational medicinal products for human use³⁴ and Regulation <u>536/2014</u> on clinical trials on medicinal products for human use³⁵).

Projects involving ethics issues may be made subject to specific ethics rules.

7. Financial and operational capacity and exclusion

Financial capacity

Applicants must have **stable and sufficient resources** to successfully implement the projects and contribute their share. Organisations participating in several projects must have sufficient capacity to implement all projects.

The financial capacity check will be carried out on the basis of the documents you will be requested to upload in the <u>Participant Register</u> during grant preparation (e.g. profit and loss account and balance sheet, business plan, audit report produced by an approved external auditor, certifying the accounts for the last closed financial year, etc). The analysis will be based on neutral financial indicators, but will also take into account other aspects, such as dependency on EU funding and deficit and revenue in previous years.

Where the application concerns a grant for which the amount exceeds EUR 750 000 per beneficiary, an audit report that is produced by an approved external auditor, where it is available, and always in cases where a statutory audit is required by Union or national

³⁴ Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (OJ L 91, 9.4.2005, p. 13).

Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

law, certifying the accounts for the last two available financial years, must be part of the application. In all other cases, the applicant shall provide a self-declaration signed by its authorised representative certifying the validity of its accounts for the last two available financial years.

The check will normally be done for all beneficiaries, except:

- public bodies (entities established as public body under national law, including local, regional or national authorities) or international organisations
- if the individual requested grant amount is not more than EUR 60 000.

If needed, it may also be done for affiliated entities.

If we consider that your financial capacity is not satisfactory, we may require:

- further information
- an enhanced financial responsibility regime, i.e. joint and several responsibility for all beneficiaries or joint and several liability of affiliated entities (see below, section 10)
- prefinancing paid in instalments
- (one or more) prefinancing guarantees (see below, section 10)

or

- propose no prefinancing
- request that you are replaced or, if needed, reject the entire proposal.

For more information, see <u>Rules for Legal Entity Validation, LEAR Appointment and Financial Capacity Assessment</u>.

Operational capacity

Applicants must have the **know-how, qualifications** and **resources** to successfully implement the projects and contribute their share (including sufficient experience in projects of comparable size and nature).

This capacity will be assessed together with the 'Quality' award criterion, on the basis of the competence and experience of the applicants and their project teams, including operational resources (human, technical and other) or, exceptionally, the measures proposed to obtain it by the time the task implementation starts.

If the evaluation of the award criterion is positive, the applicants are considered to have sufficient operational capacity.

Applicants will have to show their capacity via the following information:

- general profiles (qualifications and experiences) of the staff responsible for managing and implementing the project
- description of the consortium participants
- list of previous projects (key projects for the last 4 years) (template available in Part B).

Additional supporting documents may be requested, if needed to confirm the operational capacity of any applicant.

Public bodies, Member State organisations and international organisations are exempted from the operational capacity check.

Exclusion

Applicants which are subject to an **EU exclusion decision** or in one of the following **exclusion situations** that bar them from receiving EU funding can NOT participate³⁶:

- bankruptcy, winding up, affairs administered by the courts, arrangement with creditors, suspended business activities or other similar procedures (including procedures for persons with unlimited liability for the applicant's debts)
- in breach of social security or tax obligations (including if done by persons with unlimited liability for the applicant's debts)
- guilty of grave professional misconduct³⁷ (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant)
- committed fraud, corruption, links to a criminal organisation, money laundering, terrorism-related crimes (including terrorism financing), child labour or human trafficking (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant)
- shown significant deficiencies in complying with main obligations under an EU procurement contract, grant agreement, prize, expert contract, or similar (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant)
- guilty of irregularities within the meaning of Article 1(2) of EU Regulation <u>2988/95</u> (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant)
- created under a different jurisdiction with the intent to circumvent fiscal, social
 or other legal obligations in the country of origin or created another entity with
 this purpose (including if done by persons having powers of representation,
 decision-making or control, beneficial owners or persons who are essential for
 the award/implementation of the grant)
- intentionally and without proper justification resisted³⁸ an investigation, check or audit carried out by an EU authorising officer (or their representative or auditor), OLAF, the EPPO, or the European Court of Auditors.

Applicants will also be rejected if it turns out that³⁹:

See Articles 138 and 143 of EU Financial Regulation 2024/2509.

^{37 &#}x27;Professional misconduct' includes, in particular, the following: violation of ethical standards of the profession; wrongful conduct with impact on professional credibility; breach of generally accepted professional ethical standards; false declarations/misrepresentation of information; participation in a cartel or other agreement distorting competition; violation of IPR; attempting to influence decision-making processes by taking advantage, through misrepresentation, of a conflict of interests, or to obtain confidential information from public authorities to gain an advantage; incitement to discrimination, hatred or violence or similar activities contrary to the EU values where negatively affecting or risking to affect the performance of a legal commitment.

³⁸ 'Resisting an investigation, check or audit' means carrying out actions with the goal or effect of preventing, hindering or delaying the conduct of any of the activities needed to perform the investigation, check or audit, such as refusing to grant the necessary access to its premises or any other areas used for business purposes, concealing or refusing to disclose information or providing false information.

See Article 143 EU Financial Regulation 2024/2509.

- during the award procedure they misrepresented information required as a condition for participating or failed to supply that information
- they were previously involved in the preparation of the call and this entails a distortion of competition that cannot be remedied otherwise (conflict of interest).

8. Evaluation and award procedure

The proposals will have to follow the **standard submission and evaluation procedure** (one-stage submission + one-step evaluation)

An **evaluation committee** (potentially assisted by independent outside experts) will assess all applications. Proposals will first be checked for formal requirements (admissibility, and eligibility, see sections 5 and 6). Proposals found admissible and eligible will be evaluated (for each topic) against the operational capacity and award criteria (see sections 7 and 9) and then ranked according to their scores.

For proposals with the same score (within a topic or budget envelope) a **priority order** will be determined according to the following approach:

Successively for every group of *ex aequo* proposals, starting with the highest scored group, and continuing in descending order:

- 1) The ex aequo proposals within the same topic will be prioritised according to the scores they have been awarded for the award criterion 'Relevance'. When these scores are equal, priority will be based on their scores for the criterion 'Impact'. When these scores are equal, priority will be based on their scores for the criterion 'Quality Project design and implementation' and then for the criterion 'Quality Project team and cooperation arrangements'.
- 2) If this does not allow to determine the priority, a further prioritisation can be done by considering the overall project portfolio and the creation of positive synergies between projects, or other factors related to the objectives of the call. These factors will be documented in the panel report.
- 3) After that, the remainder of the available call budget will be used to fund projects across the different topics in order to ensure a balanced spread of the geographical and thematic coverage and while respecting to the maximum possible extent the order of merit based on the evaluation of the award criteria.

All proposals will be informed about the evaluation result (**evaluation result letter**). Successful proposals will be invited for grant preparation; the other ones will be put on the reserve list or rejected.

1 No commitment for funding — Invitation to grant preparation does NOT constitute a formal commitment for funding. We will still need to make various legal checks before grant award: legal entity validation, financial capacity, exclusion check, etc.

Grant preparation will involve a dialogue in order to fine-tune technical or financial aspects of the project and may require extra information from your side. It may also include adjustments to the proposal to address recommendations of the evaluation committee or other concerns. Full compliance will be a pre-condition for signing the grant.

If you believe that the evaluation procedure was flawed, you can submit a **complaint** (following the deadlines and procedures set out in the evaluation result letter). Please

note that notifications which have not been opened within 10 days after sending will be considered to have been accessed and that deadlines will be counted from opening/access (see also <u>Funding & Tenders Portal Terms and Conditions</u>). Please also be aware that for complaints submitted electronically, there may be character limitations.

9. Award criteria

The **award criteria** for this call are as follows:

Relevance: clarity and consistency of project, objectives and activities; extent
to which the proposal matches the priorities and objectives of the call/topic;
contribution to the EU strategic and legislative context; European/trans-national
dimension; interest for a number of countries (EU or eligible non-EU countries);
possibility to use the results in other countries; potential to develop mutual
trust/cross-border cooperation (30 points)

2. Quality:

- Project design and implementation: technical quality; logical links between the identified problems, needs and solutions proposed (logical frame concept); methodology for implementing the project (concept and methodology, timetable, risks' identification and mitigation, monitoring and evaluation); feasibility of the project within the proposed time frame; cost effectiveness and financial management (sufficient/appropriate budget for proper implementation;) (30 points)
- Project team and cooperation arrangements: quality and complementarity of the consortium and project teams; appropriate management procedures and problem-solving mechanisms for cooperating within the project teams and consortium (30 points)
- **3. Impact:** ambition and expected impact of results on target groups/general public; appropriate communication and dissemination strategy for ensuring sustainability and maximise impact; sustainability of results after EU funding ends (10 points).

Award criteria	Minimum pass score	Maximum score
Relevance	21	30
Quality — Project design and implementation	21	30
Quality — Project team and cooperation arrangements	21	30
Impact	7	10
Overall (pass) scores	70	100

Maximum points: 100 points.

Individual thresholds per criterion: 21/30, 21/30, 21/30 and 7/10 points.

Overall threshold: 70 points.

Proposals that pass the individual thresholds AND the overall threshold will be considered for funding — within the limits of the available budget (i.e. up to the budget ceiling). Other proposals will be rejected.

10. Legal and financial set-up of the Grant Agreements

If you pass evaluation, your project will be invited for grant preparation, where you will be asked to prepare the Grant Agreement together with the EU Project Officer.

This Grant Agreement will set the framework for your grant and its terms and conditions, in particular concerning deliverables, reporting and payments.

The Model Grant Agreement that will be used (and all other relevant templates and quidance documents) can be found on Portal Reference Documents.

Starting date and project duration

The project starting date and duration will be fixed in the Grant Agreement (Data Sheet, point 1). Normally the starting date will be after grant signature. A retroactive starting date can be granted exceptionally for duly justified reasons but never earlier than the proposal submission date.

Project duration: see section 6 above.

Milestones and deliverables

The milestones and deliverables for each project will be managed through the Portal Grant Management System and will be reflected in Annex 1 of the Grant Agreement.

The following deliverables will be mandatory for all projects:

- project websites (presentation of the project on the participants' websites, informing on the objectives and results of the project)
- project leaflet (informing on the objectives and results of the project)
- dissemination report
- evaluation report

Specific mandatory deliverables and/or milestones per topic:

EU4H-2026-SANTE-PJ-01 - Call for proposals to pilot and implement cancer screening programmes for gastric cancer (CR/CV&NCD-g-25-12)

Deliverables:

- report on ongoing (pilot) programmes and implementation studies for gastric cancer screening in Member States;
- report on latest available evidence on benefits and harms, outcomes, quality assurance and cost-effectiveness of gastric cancer screening originating from the ongoing (pilot) programmes and implementation studies;

- report on the potential and the actual use of AI in ongoing gastric cancer screening (pilot) programmes and implementation studies (both within and outside of the project); and
- report on how the project will build on results of previous relevant EU-funded projects (particularly TOGAS and Accelerating gastric cancer reduction in Europe through Helicobacter pylori eradication ('EUROHELICAN') of the 2021 EU4Health work programme, action DP/C-g-08.6.1⁵²), on how the findings of the previous pilot activities have informed the new studies, and on how synergies with parallel actions and initiatives will be used particularly:
 - parallel projects on lung and prostate cancer screening,
 - Joint Action EUCanScreen, to ensure alignment with Member States' needs and priorities and to take into account findings generated through relevant work packages,
 - upcoming work on the third EU Cancer Screening Monitoring Report, to ensure alignment on data collection and monitoring activities,
 - and the planned Commission Initiative on Gastric Cancer Screening, to ensure alignment with development of European guidelines and quality assurance scheme.

Milestones

- establishment of network of gastric cancer screening experts and relevant representatives from European medical societies and patient organisations.
- launch of gastric cancer implementation studies, including at least one implementation study, or sub-topic within one study, on the use of AI where feasible.
- inclusion of an equity perspective (how to reach underrepresented or vulnerable subpopulations).

EU4H-2026-SANTE-PJ-02 - Call for proposals to pilot and implement cancer screening programmes for lung cancer (CR/CV&NCD -g-25-13)

Deliverables

- report on ongoing (pilot) programmes and implementation studies for lung cancer screening in Member States;
- report on latest available evidence on benefits and harms, outcomes, quality assurance and cost-effectiveness of lung cancer screening originating from the ongoing (pilot) programmes and implementation studies;
- report on the potential and the actual use of AI in ongoing lung cancer screening (pilot) programmes and implementation studies (both within and outside of the project);
- report on how the project will build on results of previous relevant EU-funded projects (particularly SOLACE), on how the findings of the previous pilot activities have informed the new studies, and on how synergies with parallel actions and initiatives will be used particularly:
 - o parallel projects on prostate and gastric cancer screening,

- Joint Action EUCanScreen, to ensure alignment with Member States' needs and priorities and to take into account findings generated through relevant work packages,
- European Cancer Imaging Initiative, in particular the Cancer Image Europe platform, to foster the AI uptake in lung cancer screening,
- o upcoming work on the third EU Cancer Screening Monitoring Report, to ensure alignment on data collection and monitoring activities,
- o and the planned Commission Initiative on Lung Cancer Screening, to ensure alignment with development of European guidelines and quality assurance scheme.

Milestones

- establishment of a network of lung cancer screening experts and relevant representatives from European medical societies and patient organisations;
- launch of lung cancer screening implementation studies, including at least one implementation study, or sub-topic within one study, on the use of AI;
- inclusion of smoking cessation support activities in the pilot studies;
- inclusion of an equity perspective (how to reach underrepresented or vulnerable subpopulations);

EU4H-2026-SANTE-PJ-03 - Call for proposals to pilot and implement cancer screening programmes for prostate cancer (CR/CV&NCD-g-25-14)

Deliverables

- report on ongoing (pilot) programmes and implementation studies for prostate cancer screening in Member States;
- report on latest available evidence on benefits and harms, outcomes, quality assurance and cost-effectiveness of prostate cancer screening;
- report on the potential and the actual use of AI in ongoing prostate cancer screening (pilot) programmes and implementation studies (both within and outside of the project); and
- report on how the project will build on results of previous relevant EU-funded projects (particularly PRAISE-U), on how the findings of the previous pilot activities have informed the new studies, and on how synergies with parallel actions and initiatives will be used particularly:
 - o Parallel projects on lung and gastric cancer screening,
 - Joint Action EUCanScreen, to ensure alignment with Member States' needs and priorities and to take into account findings generated through relevant work packages,
 - European Cancer Imaging Initiative, in particular the Cancer Image Europe platform, to foster AI uptake in prostate cancer screening,
 - o planned work on the third EU Cancer Screening Monitoring Report, to ensure alignment on data collection and monitoring activities,
 - planned Commission Initiative on Prostate Cancer Screening, to ensure alignment with development of European guidelines and quality assurance scheme.

Milestones

- establishment of a network of prostate cancer screening experts and relevant representatives from European medical societies and patient organisations;
- launch of prostate cancer implementation studies, including at least one implementation study, or sub-topic within one study, on the use of AI where feasible;
- inclusion of an equity perspective (how to reach underrepresented or vulnerable subpopulations);

EU4H-2026-SANTE-PJ-04 - A European flagship initiative leveraging AI and health data for cardiovascular health and related non-communicable diseases: Advancing Risk Prediction, Prevention, Treatments, Personalised Care and Rehabilitation (CR/CV&NCD-g-25-16)

Deliverables

- Strategic roadmap for AI adoption in cardiovascular and related chronic disease care (to be delivered within the first 6–9 months).
- Minimum technical specifications for cardiovascular datasets (including structured phenotypes and metadata standards).
- Operational launch of the federated data infrastructure building on the EHDS framework.
- Interim report on piloted AI tools and their performance in real-world clinical settings.
- Blueprint and deployment protocols for large-scale integration of validated AI solutions.
- Final evidence-based clinical and organisational guidelines for AI integration into healthcare settings

Milestones

Completion of stakeholder consultation and dissemination campaign.

EU4H-2026-SANTE-PJ-05 - Call for proposals on lifelong prevention for a healthy life with focus on cardiovascular diseases (CR/CV&NCD-g-25-18)

Specific mandatory **deliverables** are expected to be achieved through the implementation of a lifelong prevention plan, which will focus on reducing the risk of cardiovascular disease and diabetes among vulnerable populations, with a particular emphasis on women.

- report on pilot testing and implementation of best and promising practices in early detection, screening, and prevention of cardiovascular diseases and diabetes, as identified through the EU Best Practice Portal, resulting in the development of concrete support tools to enhance national authorities' capacity in these areas.
- report on design, implementation end evaluation of community-level actions to address lifelong prevention of non-communicable diseases and related risk factors, i.e., evidence-based programmes that work at primary care and community level with demonstrated positive effect on reducing the risk of

- developing cardiovascular diseases and diabetes in vulnerable groups, such as women.
- report on design and implementation of digital public health interventions (i.e., through self-assessment tools, mobile outreach, or targeted digital awareness campaigns) to identify and engage individuals at risk of developing cardiovascular diseases and diabetes, with a focus on vulnerable populations, such as women.
- report on targeted awareness campaigns, including events, designed to reach vulnerable groups, such as women, and build capacity among stakeholders to prevent non-communicable diseases and their risk factors,
- report on capacity-building events to improve health literacy targeting vulnerable groups, more specifically women, to support community and primary care level interventions on detecting early signs to prevent and manage cardiovascular diseases and diabetes.

EU4H-2026-SANTE-PJ-06 - Call for proposals to support the development of a medicine pricing, reimbursement and access tracker through the EURIPID database (HS-g-25-20)

Deliverables

- **P&R tracker platform specification document** Technical and functional specification for the "pricing and reimbursement (P&R) tracker"
- **Prototype of P&R tracker platform** Functional prototype of the P&R tracker with initial populated data for selected Member States.
- **Finalised P&R tracker platform** Fully developed, tested, and operational P&R tracker platform incorporating feedback from the prototype phase, ready for full deployment and use by Member States.
- Access dashboards Interactive dashboards building on OECD indicators, covering medicine availability (e.g., coverage status, time-to-reimbursement), affordability (e.g., treatment cost), and accessibility (e.g., uptake/consumption).
- **Annual trend analysis report** Comprehensive annual report analysing trends in access to medicines in the Union, based on the data available in EURIPID and collected through the P&R tracker or dedicated surveys.
- Data sharing automation framework with EURIPID Documented framework to support automated and secure data exchange between Member States and EURIPID. It includes the development of an API interface, machine-to-machine interaction protocols, and data standardisation guidelines.
- **Interoperability integration report** -Technical report on enhanced interoperability between EURIPID and other EU databases (e.g., European Shortages Medicine Platform, SPOR, Product Management Service), including recommendations for integration with the European Health Data Space.
- Webinars for users A series of webinars to present EURIPID functionalities, new tools, explain access dashboards and the P&R tracker, and provide training to relevant users.
- **User guides and standardisation manual** Updated documentation including user guides, technical manuals, and a standardisation manual to ensure harmonised implementation across Member States, including for the P&R tracker and automation framework.

EU4H-2026-SANTE-PJ-07 - Call for proposals for a programme on orphan medical devices, in particular targeting paediatric patients (HS-g-25-24)

Deliverables

• Report on the advancement of the devices supported for further development and expected future milestones, up to an including market access.

EU4H-2026-SANTE-PJ-08 - Call for proposals for health data for biotech innovation leveraging the European Health Data Space (DI-g-25-31)

Deliverables

- Stakeholder mapping and organisation of stakeholder fora that will bring together biotech industry, research institutions, healthcare providers, patient organisations, regulatory bodies and AI Factories.
- **Landscape analysis of** the current state of leveraging health data for AI in the biotech sector and identification of the most relevant health datasets for the biotech sector (by Month 6).
- **A strategic roadmap** for the development, deployment, and scale-up of effective AI solutions in the biotech sector, including recommendations for policymakers, industry leaders, and researchers.
- **Recommendations and guideline** on standardized data formats and frameworks from existing data and research infrastructure relevant to the biotech sector, that can be used to improve health data quality.
- Report and lessons learnt from the use cases.

Milestones

• Use Cases to pilot the role of health data infrastructures under the EHDS framework: This involves analysing and piloting the roles, and the potential federation of, specific health data infrastructures (genomic, cancer imaging, and brain) within the EHDS framework for the development and deployment of AI tools in the biotech sector. Incorporate AI technological advancements in collaboration with the use of the EHDS infrastructure.

EU4H-2026-SANTE-PJ-09 - Call for proposals to contribute to the organisation of conferences (OA-g-25-33)

Deliverables

- relevant online, electronic and limited printed materials during and post conference
- summary report of the feedback survey from a broad audience participating onsite and online to the event
- report on the streaming live services (at least for some parts of the event e.g. plenary sessions), recordings (in line with GDPR)
- report on relevant social media activity such as Twitter, LinkedIn, and other relevant social media

The grant parameters (maximum grant amount, funding rate, total eligible costs, etc) will be fixed in the Grant Agreement (Data Sheet, point 3 and art 5).

Requested budget (maximum grant amount): see section 6 above.

The grant will be a budget-based mixed actual cost grant (actual costs, with unit cost and flat-rate elements). This means that it will reimburse ONLY certain types of costs (eligible costs) and costs that were actually incurred for your project (NOT the budgeted costs). For unit costs and flat-rates, you can charge the amounts calculated as explained in the Grant Agreement (see art 6 and Annex 2 and 2a).

The costs will be reimbursed at the funding rate fixed in the Grant Agreement (**60%**). You can apply for a higher project funding rate (**80%**) if your project is of 'exceptional utility', i.e. concerns:

- actions where at least 30 % of the budget is allocated to Member States (or EU4H associated countries) whose GNI per inhabitant is less than 90% of the EU average or
- actions with bodies from at least 14 Member States (or EU4H associated countries) and where at least four are from Member States (or EU4H associated countries) whose GNI per inhabitant is less than 90% of the EU average.

Grants may NOT produce a profit (i.e. surplus of revenues + EU grant over costs). Forprofit organisations must declare their revenues and, if there is a profit, we will deduct it from the final grant amount (see art 22.3).

Moreover, please be aware that the final grant amount may be reduced in case of non-compliance with the Grant Agreement (e.g. improper implementation, breach of obligations, etc).

Budget categories and cost eligibility rules

The budget categories and cost eligibility rules are fixed in the Grant Agreement (Data Sheet, point 3, art 6 and Annex 2).

Budget categories for this call:

- A. Personnel costs
 - A.1 Employees
 - A.2 Natural persons under direct contract
 - A.3 Seconded persons
 - A.4 SME owners and natural person beneficiaries
- B. Subcontracting costs
- C. Purchase costs
 - C.1 Travel and subsistence
 - C.2 Equipment
 - C.3 Other goods, works and services
- D. Other cost categories
 - D.1 Financial support to third parties ONLY for the following topics:

EU4H-2026-SANTE-PJ-04 - A European flagship initiative leveraging AI and health data for cardiovascular health and related non-communicable

diseases: Advancing Risk Prediction, Prevention, Treatments, Personalised Care and Rehabilitation (CR/CV&NCD-g-25-16)

EU4H-2026-SANTE-PJ-08 - Call for proposals for health data for biotech innovation leveraging the European Health Data Space (DI-g-25-31)

E. Indirect costs

Specific cost eligibility conditions for this call:

- personnel costs:
 - SME owner/natural person unit cost⁴⁰: Yes
- travel and subsistence unit cost⁴¹: Yes⁴²
- equipment costs:
 - o Depreciation
 - EU4H-2026-SANTE-PJ-04 A European flagship initiative leveraging AI and health data for cardiovascular health and related non-communicable diseases: Advancing Risk Prediction, Prevention, Treatments, Personalised Care and Rehabilitation (CR/CV&NCD-g-25-16)
 - EU4H-2026-SANTE-PJ-05 Call for proposals on lifelong prevention for a healthy life with focus on cardiovascular diseases (CR/CV&NCD-g-25-18)
 - EU4H-2026-SANTE-PJ-06 Call for proposals to support the development of a medicine pricing, reimbursement and access tracker through the EURIPID database (HS-g-25-20)
 - EU4H-2026-SANTE-PJ-07 Call for proposals for a programme on orphan medical devices, in particular targeting paediatric patients (HS-g-25-24)
 - EU4H-2026-SANTE-PJ-08 Call for proposals for health data for biotech innovation leveraging the European Health Data Space (DI-g-25-31)
 - EU4H-2026-SANTE-PJ-09 Call for proposals to contribute to the organisation of conferences (OA-g-25-33)

Commission <u>Decision</u> of 20 October 2020 authorising the use of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary for the work carried out by themselves under an action or work programme (C(2020)7115).

⁴¹ Commission <u>Decision</u> of 12 January 2021 authorising the use of unit costs for travel, accommodation and subsistence costs under an action or work programme under the 2021-2027 multi-annual financial framework (C(2021)35).

See <u>EU Grants AGA — Annotated Grant Agreement</u>, art 6 on eligible costs: travel and subsistence costs must be declared using the unit cost according to Annex 2a of the grant agreement. If a particular instance of travel, accommodation or subsistence in the action is not covered by one of the unit costs mentioned in Decision C(2021)35 the actual costs may be used.

Full cost

- EU4H-2026-SANTE-PJ-01 Call for proposals to pilot and implement cancer screening programmes for gastric cancer (CR/CV&NCD-g-25-12)
- EU4H-2026-SANTE-PJ-02 Call for proposals to pilot and implement cancer screening programmes for lung cancer (CR/CV&NCD -g-25-13)
- EU4H-2026-SANTE-PJ-03 Call for proposals to pilot and implement cancer screening programmes for prostate cancer (CR/CV&NCD-g-25-14)
- other cost categories:
 - costs for financial support to third parties: allowed for grants or similar; maximum amount per third party EUR 60 000: allowed **ONLY for the following topics:**

EU4H-2026-SANTE-PJ-04 - A European flagship initiative leveraging AI and health data for cardiovascular health and related non-communicable diseases: Advancing Risk Prediction, Prevention, Treatments, Personalised Care and Rehabilitation (CR/CV&NCD-g-25-16)

EU4H-2026-SANTE-PJ-08 - Call for proposals for health data for biotech innovation leveraging the European Health Data Space (DI-g-25-31)

- indirect cost flat-rate: 7% of the eligible direct costs (categories A-D, except volunteers costs and exempted specific cost categories, if any)
- VAT: non-deductible/non-refundable VAT is eligible (but please note that since 2013 VAT paid by beneficiaries that are public bodies acting as public authority is NOT eligible)

– other:

- in-kind contributions for free are allowed, but cost-neutral, i.e. they cannot be declared as cost
- kick-off meeting: costs for kick-off meeting organised by the granting authority are eligible (travel costs for maximum 2 persons, return ticket to Brussels and accommodation for one night) only if the meeting takes place after the project starting date set out in the Grant Agreement; the starting date can be changed through an amendment, if needed
- project websites: communication costs for presenting the project on the participants' websites or social media accounts are eligible (e.g. acquiring domain name, personal costs for feeding and maintaining the website during the project, etc); costs for separate project websites are not eligible
- other ineligible costs: Yes, costs for infrastructure and land purchase.

Reporting and payment arrangements

The reporting and payment arrangements are fixed in the Grant Agreement (Data Sheet, point 4 and art 21 and 22).

After grant signature, you will normally receive a **prefinancing** to start working on the project (float of normally **50%** of the maximum grant amount; exceptionally less or no prefinancing). The prefinancing will be paid 30 days from entry into force/10 days before starting date/financial guarantee (if required) — whichever is the latest.

For projects under topic **EU4H-2026-SANTE-PJ-09 - Call for proposals to contribute to the organisation of conferences OA-g-25-33):** There will be no interim payments.

For all remaining topics: There will be one or more **interim payments** (with detailed cost reporting).

Payment of the balance: At the end of the project, we will calculate your final grant amount. If the total of earlier payments is higher than the final grant amount, we will ask you (your coordinator) to pay back the difference (recovery).

All payments will be made to the coordinator.

⚠ Please be aware that payments will be automatically lowered if you or one of your consortium members has outstanding debts towards the EU (granting authority or other EU bodies). Such debts will be offset by us — in line with the conditions set out in the Grant Agreement (see art 22).

Please also note that you are responsible for **keeping records** on all the work done and the costs declared.

Prefinancing quarantees

If a prefinancing guarantee is required, it will be fixed in the Grant Agreement (*Data Sheet, point 4*). The amount will be set during grant preparation and it will normally be equal or lower than the prefinancing for your grant.

The guarantee should be in euro and issued by an approved bank/financial institution established in an EU Member State. If you are established in a non-EU country and would like to provide a guarantee from a bank/financial institution in your country, please contact us (this may be exceptionally accepted, if it offers equivalent security).

Amounts blocked in bank accounts will NOT be accepted as financial guarantees.

Prefinancing guarantees are normally requested from the coordinator, for the consortium. They must be provided during grant preparation, in time to make the prefinancing (scanned copy via Portal AND original by post).

If agreed with us, the bank guarantee may be replaced by a guarantee from a third party.

The guarantee will be released at the end of the grant, in accordance with the conditions laid down in the Grant Agreement (art 23).

Certificates

Depending on the type of action, size of grant amount and type of beneficiaries, you may be requested to submit different certificates. The types, schedules and thresholds for each certificate are fixed in the Grant Agreement (*Data Sheet, point 4 and art 24*).

Liability regime for recoveries

The liability regime for recoveries will be fixed in the Grant Agreement (Data Sheet, point 4.4 and art 22).

For beneficiaries, it is one of the following:

limited joint and several liability with individual ceilings — each beneficiary up to their maximum grant amount

 unconditional joint and several liability — each beneficiary up to the maximum grant amount for the action

or

individual financial responsibility — each beneficiary only for their own debts.

In addition, the granting authority may require joint and several liability of affiliated entities (with their beneficiary).

<u>Provisions concerning the project implementation</u>

Ethics rules: see Model Grant Agreement (art 14 and Annex 5)

IPR rules: see Model Grant Agreement (art 16 and Annex 5):

- list of background: Yes
- rights of use on results: Yes
- access to results for policy purposes: Yes
- access rights to ensure continuity and interoperability obligations: Yes

Communication, dissemination and visibility of funding: see Model Grant Agreement (art 17 and Annex 5):

- communication and dissemination plan: Yes
- additional communication and dissemination activities: Yes

Specific rules for carrying out the action: see Model Grant Agreement (art 18 and Annex 5):

- durability:
 - o No
- EU4H-2026-SANTE-PJ-04 A European flagship initiative leveraging AI and health data for cardiovascular health and related non-communicable diseases: Advancing Risk Prediction, Prevention, Treatments, Personalised Care and Rehabilitation (CR/CV&NCD-g-25-16)
- EU4H-2026-SANTE-PJ-05 Call for proposals on lifelong prevention for a healthy life with focus on cardiovascular diseases (CR/CV&NCD-g-25-18)
- EU4H-2026-SANTE-PJ-06 Call for proposals to support the development of a medicine pricing, reimbursement and access tracker through the EURIPID database (HS-g-25-20)
- EU4H-2026-SANTE-PJ-07 Call for proposals for a programme on orphan medical devices, in particular targeting paediatric patients (HS-g-25-24)
- EU4H-2026-SANTE-PJ-08 Call for proposals for health data for biotech innovation leveraging the European Health Data Space (DI-g-25-31)

EU4H-2026-SANTE-PJ-09 - Call for proposals to contribute to the organisation of conferences (OA-g-25-33)

Yes

- EU4H-2026-SANTE-PJ-01 Call for proposals to pilot and implement cancer screening programmes for gastric cancer (CR/CV&NCD-g-25-12)
- EU4H-2026-SANTE-PJ-02 Call for proposals to pilot and implement cancer screening programmes for lung cancer (CR/CV&NCD -g-25-13)
- EU4H-2026-SANTE-PJ-03 Call for proposals to pilot and implement cancer screening programmes for prostate cancer (CR/CV&NCD-q-25-14)
- specific rules for blending operations: No

Other specificities

Consortium agreement: Yes

Non-compliance and breach of contract

The Grant Agreement (chapter 5) provides for the measures we may take in case of breach of contract (and other non-compliance issues).



For more information, see AGA — Annotated Grant Agreement.

11. How to submit an application

All proposals must be submitted directly online via the Funding & Tenders Portal Electronic Submission System. Paper applications are NOT accepted.

Submission is a **2-step process**:

a) create a user account and register your organisation

To use the Submission System (the only way to apply), all participants need to create an EU Login user account.

Once you have an EULogin account, you can register your organisation in the Participant Register. When your registration is finalised, you will receive a 9-digit participant identification code (PIC).

b) submit the proposal

Access the Electronic Submission System via the Topic page in the Calls for proposals section (or, for calls sent by invitation to submit a proposal, through the link provided in the invitation letter).

Submit your proposal in 3 parts, as follows:

Part A includes administrative information about the applicant organisations (future coordinator, beneficiaries, affiliated entities and associated partners) and the summarised budget for the proposal. Fill it in directly online

- Part B (description of the action) covers the technical content of the proposal.
 Download the mandatory word template from the Submission System, fill it in and upload it as a PDF file
- Annexes (see section 5). Upload them as PDF file (single or multiple depending on the slots). Excel upload is sometimes possible, depending on the file type.

The proposal must keep to the **page limits** (see section 5); excess pages will be disregarded.

Documents must be uploaded to the **right category** in the Submission System, otherwise the proposal may be considered incomplete and thus inadmissible.

The proposal must be submitted **before the call deadline** (see section 4). After this deadline, the system is closed and proposals can no longer be submitted.

Once the proposal is submitted, you will receive a **confirmation e-mail** (with date and time of your application). If you do not receive this confirmation e-mail, it means your proposal has NOT been submitted. If you believe this is due to a fault in the Submission System, you should immediately file a complaint via the IT Helpdesk webform, explaining the circumstances and attaching a copy of the proposal (and, if possible, screenshots to show what happened).

Details on processes and procedures are described in the Online Manual. The Online Manual also contains the links to FAQs and detailed instructions regarding the Portal Electronic Exchange System.

12. Help

As far as possible, **please try to find the answers you need yourself**, in this and the other documentation (we have limited resources for handling direct enquiries):

- Online Manual
- Topic Q&A on the Topic page (for call-specific questions in open calls; not applicable for actions by invitation)
- Portal FAQ (for general questions).

Please also consult the Topic page regularly, since we will use it to publish call updates. (For invitations, we will contact you directly in case of a call update).

Contact

For individual questions on the Portal Submission System, please contact the $\underline{\text{IT}}$ $\underline{\text{Helpdesk}}$.

Non-IT related questions should be sent to the following email address: <u>HADEA-HP-CALLS@ec.europa.eu</u>.

Please indicate clearly the reference of the call and topic to which your question relates (see cover page).

13. Important



IMPORTANT

- **Don't wait until the end** Complete your application sufficiently in advance of the deadline to avoid any last minute technical problems. Problems due to last minute submissions (e.g. congestion, etc) will be entirely at your risk. Call deadlines can NOT be extended.
- Consult the Portal Topic page regularly. We will use it to publish updates and additional information on the call (call and topic updates).
- Funding & Tenders Portal Electronic Exchange System By submitting the application, all participants accept to use the electronic exchange system in accordance with the Portal Terms & Conditions.
- **Registration** Before submitting the application, all beneficiaries, affiliated entities and associated partners must be registered in the Participant Register. The participant identification code (PIC) (one per participant) is mandatory for the Application Form.
- Consortium roles When setting up your consortium, you should think of organisations that help you reach objectives and solve problems.
 - The roles should be attributed according to the level of participation in the project. Main participants should participate as beneficiaries or affiliated entities; other entities can participate as associated partners, subcontractors, third parties giving in-kind contributions. Associated partners and third parties giving in-kind contributions should bear their own costs (they will not become formal recipients of EU funding). Subcontracting should normally constitute a limited part and must be performed by third parties (not by one of the beneficiaries/affiliated entities). Subcontracting going beyond 30% of the total eligible costs must be justified in the application.
- Coordinator In multi-beneficiary grants, the beneficiaries participate as consortium (group of beneficiaries). They will have to choose a coordinator, who will take care of the project management and coordination and will represent the consortium towards the granting authority. In mono-beneficiary grants, the single beneficiary will automatically be coordinator.
- **Affiliated entities** Applicants may participate with affiliated entities (i.e. entities linked to a beneficiary which participate in the action with similar rights and obligations as the beneficiaries, but do not sign the grant and therefore do not become beneficiaries themselves). They will get a part of the grant money and must therefore comply with all the call conditions and be validated (just like beneficiaries); but they do not count towards the minimum eligibility criteria for consortium composition (if any). If affiliated entities participate in your project, please do not forget to provide documents demonstrating their affiliation link to your organisation as part of your application.
- **Associated partners** Applicants may participate with associated partners (i.e. partner organisations which participate in the action but without the right to get grant money). They participate without funding and therefore do not need to be validated.
- **Consortium agreement** For practical and legal reasons it is recommended to set up internal arrangements that allow you to deal with exceptional or unforeseen circumstances (in all cases, even if not mandatory under the Grant Agreement). The consortium agreement also gives you the possibility to redistribute the grant money according to your own consortium-internal principles and parameters (for instance, one beneficiary can reattribute its grant money to another beneficiary). The consortium agreement thus allows you to customise the EU grant to the needs inside your consortium and can also help to protect you in case of disputes.

- **Balanced project budget** Grant applications must ensure a balanced project budget and sufficient other resources to implement the project successfully (e.g. own contributions, income generated by the action, financial contributions from third parties, etc). You may be requested to lower your estimated costs, if they are ineligible (including excessive).
- **Completed/ongoing projects** Proposals for projects that have already been completed will be rejected; proposals for projects that have already started will be assessed on a case-by-case basis (in this case, no costs can be reimbursed for activities that took place before the project starting date/proposal submission).
- **No-profit rule** Grants may NOT give a profit (i.e. surplus of revenues + EU grant over costs). This will be checked by us at the end of the project.
- **No cumulation of funding/no double funding** It is strictly prohibited to cumulate funding from the EU budget (except under 'EU Synergies actions'). Outside such Synergies actions, any given action may receive only ONE grant from the EU budget and cost items may under NO circumstances be declared under two EU grants; projects must be designed as different actions, clearly delineated and separated for each grant (without overlaps).
- **Combination with EU operating grants** Combination with EU operating grants is possible, if the project remains outside the operating grant work programme and you make sure that cost items are clearly separated in your accounting and NOT declared twice (see AGA Annotated Grant Agreement, art 6.2.E).
- **Multiple proposals** Applicants may submit more than one proposal for *different* projects under the same call (and be awarded funding for them).

Organisations may participate in several proposals.

BUT: if there are several proposals for *very similar* projects, only one application will be accepted and evaluated; the applicants will be asked to withdraw the others (or they will be rejected).

- Resubmission Proposals may be changed and re-submitted until the deadline for submission.
- **Rejection** By submitting the application, all applicants accept the call conditions set out in this this Call document (and the documents it refers to). Proposals that do not comply with all the call conditions will be rejected. This applies also to applicants: All applicants need to fulfil the criteria; if any one of them doesn't, they must be replaced or the entire proposal will be rejected.
- **Cancellation** There may be circumstances which may require the cancellation of the call. In this case, you will be informed via a call or topic update. Please note that cancellations are without entitlement to compensation.
- **Language** You can submit your proposal in any official EU language (project abstract/summary should however always be in English). For reasons of efficiency, we strongly advise you to use English for the entire application. If you need the call documentation in another official EU language, please submit a request within 10 days after call publication (for the contact information, see section 12).

• **Transparency** — In accordance with Article 38 of the <u>EU Financial Regulation</u>, information about EU grants awarded is published each year on the <u>Europa website</u>.

This includes:

- beneficiary names
- beneficiary addresses
- the purpose for which the grant was awarded
- the maximum amount awarded.

The publication can exceptionally be waived (on reasoned and duly substantiated request), if there is a risk that the disclosure could jeopardise your rights and freedoms under the EU Charter of Fundamental Rights or harm your commercial interests.

Data protection — The submission of a proposal under this call involves the collection, use and processing of personal data. This data will be processed in accordance with the applicable legal framework. It will be processed solely for the purpose of evaluating your proposal, subsequent management of your grant and, if needed, programme monitoring, evaluation and communication. Details are explained in the <u>Funding & Tenders Portal Privacy Statement</u>.