



EU4Health Programme (EU4H)

Call for proposals

EU4H Action Grants 2024 (EU4H-2024-PJ-02)

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EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HaDEA)

HaDEA.A – Health and Food **A.1 –EU4Health**

CALL FOR PROPOSALS

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0. Introduction

This is a call for proposals for EU **action grants** in the field of cancer under the **EU4Health Programme (EU4H)**.

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

- Regulation 2018/1046 (<u>EU Financial Regulation</u>)
- the basic act (EU4H Programme Regulation <u>2021/522</u>1).

The call is launched in accordance with the 2024 Work Programme² and will be managed by the **European Health and Digital Executive Agency**, (HaDEA) ('Agency').

The call covers the following **topics**:

- EU4H-2024-PJ-02-1 Call for Proposal to support integration of cancer images into the federated pan-European infrastructure to foster screening programmes - CR-g-24-37
- EU4H-2024-PJ-02-2 Call for Proposals to increase health literacy for cancer prevention and care - CR-g-24-39
- EU4H-2024-PJ-02-3 Call for proposals on the development of social services for psychosocial support and rehabilitation for children and their families in paediatric oncology clinics in Member States and countries associated to the EU4Health Programme - CR-g-24-43
- EU4H-2024-PJ-02-4 Call for Proposals on EU Network of Youth Cancer Survivors - CR-g-24-45

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:

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).

Commission Implementing Decision C(2023) 8524 final of 5 December 2023 concerning the adoption of the work programme for 2024 and the financing decision for the implementation of the EU4health Programme.

- 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 Online Manual 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).

You are also encouraged to visit the <u>DG SANTE website</u> to consult the list of projects funded previously.

1. Background

On 24 March 2021, the EU4Health Regulation was adopted as part of the EU Multiannual Financial Framework for the 2021-2027 period. The EU4Health Regulation established 'the EU4Health Programme'. This marks an important step towards making available instruments and solutions to support Member States in building stronger, more resilient and accessible health systems.

The EU4Health Programme represents an unprecedented level of financial commitment for the EU in health in comparison with previous health programmes. The Programme is EU's response to the current public health emergency that will make a significant contribution to the post-COVID-19 recovery aiming to:

- improve public health in the Union through disease prevention and health promotion, as well as international health initiatives and cooperation;
- protect people from serious cross-border health threats through prevention, preparedness and response to cross-border health threats; complementing national stockpiling of essential crisis-relevant products; and establishing a reserve of medical, healthcare and support staff;
- improve access to medicinal products, medical devices and crisis-relevant products by encouraging sustainable production and supply chains and innovation in the Union and efficient use of medicinal products;
- strengthen the national health systems through improved health data use and reuse, development of digital tools and services, digital transformation of healthcare; enhancing access to healthcare; developing and implementing EU health legislation and evidence-based decision making; and integrated work among Member States' health systems.

EU4H-2024-PJ-02-1 — Call for Proposal to support integration of cancer images into the federated pan-European infrastructure to foster screening programmes - CR-g-24-37

The European Cancer Imaging Initiative³ is a Flagship of the Europe's Beating Cancer Plan⁴. The aim of the initiative is to foster innovation and deployment of digital technologies in cancer treatment and care, to achieve more precise and faster clinical decision-making, diagnostics, treatments, and predictive medicine for cancer patients. In the framework of the initiative, a pan-European federated infrastructure of deidentified, real-world imaging data of cancer patients is deployed under the EUCAIM⁵ project. The data will come from Union-level and national initiatives, hospital networks, and research repositories and infrastructures. The infrastructure will be used by clinicians, researchers, and innovators to develop and test Artificial Intelligence (AI) algorithms and AI-based solutions for more precise and faster clinical decision-making, diagnostics, treatments, and predictive medicine in cancer care.

The Council Recommendation of 9 December 2022 on strengthening prevention through early detection: A new EU approach on cancer screening replacing Council Recommendation 2003/878/EC⁶ extends the recommended screening to new cancer types and sets ambitious targets for cancer screening in Europe. In its Recommendation, the Council asks Member States to collect, manage and evaluate the data, and to consider, where appropriate, making the data available for cancer research, including implementation research and for the development of improved technological possibilities for early cancer diagnosis and prevention, in full compliance with applicable data protection legislation. The implementation of this Council Recommendation is being supported by EU4Health funded projects such as SOLACE (Strengthening the screening of Lung Cancer in Europe)⁷, and Direct grants to Member States' authorities: Implementation of cancer screening programmes (CR-g-23-38) under the 2023 EU4Health annual work programme⁸.

It is important to link the two actions of the Europe's Beating Cancer Plan, in particular since the AI-based technological solutions for imaging data can support Member States in the implementation of screening programmes. On the other hand, imaging data representative of the European population is necessary to develop transferable AI-based solutions that can cover different European regions and benefit the European population.

The proposed European Health Data Space ('EHDS')⁹ aims at advancing the use and reuse of health data for healthcare provision, research, innovation, policy-making and regulatory activities. The health data access bodies that would be set up in the context of the EHDS would, once the EHDS Regulation has been adopted, facilitate the secondary uses of health data. Secondary use means further use beyond healthcare provision, which can help, for example, advance medical technologies for cancer with the support of new AI models.

EU4H-2024-PJ-02-2 — Call for Proposals to increase health literacy for cancer prevention and care - CR-g-24-39

³ European Cancer Imaging Initiative | Shaping Europe's digital future (europa.eu).

⁴ Europe's Beating Cancer Plan

⁵ <u>www.cancerimage.eu</u>

⁶ OJ C 473, 13.12.2022, p. 1.

⁷ SOLACE (europa.eu).

⁸ EU4Health 2023 WP (CR-g-23-38).

⁹ Proposal for a Regulation of the European Parliament and of the Council of the European Health Data Space. COM (2022)197 final.

Improving understanding of risk factors to health and of health determinants is vital to improve health outcomes, especially for complex diseases like cancer. The Europe's Beating Cancer Plan includes actions to give people the information and tools they need to make healthier choices and to promote cooperation between health and social services and the community.

Health literacy is an essential part of quality, patient-centred care. Cancer health literacy poses a particular set of challenges compared to other types of health literacy, as patient decisions and treatment schedules are often complex, and timely decision-making can be critical. Clear, efficient communication is vital to help patients understand and make decisions about their treatment and to manage the side-effects of cancer treatment.

One of the policy objectives of Europe's Beating Cancer Plan is to launch a project on 'Health Literacy for Cancer Prevention and Care' to develop and share best practice to strengthen health literacy on cancer prevention and care programmes, with a focus on disadvantaged groups, including refugees and displaced persons from Ukraine. In addition to influencing prevention, screening and treatment decisions, low health literacy can negatively affect the use of palliative care and end-of-life services. This project is expected to establish the necessary links and contribute to the creation of the future European Cancer Patient Digital Centre¹⁰, which is an initiative launched under the EU Cancer Mission.

Using digital tools and solutions in cancer prevention and care can contribute to improving cancer health literacy, especially for disadvantaged groups and in disadvantage regions, increasing patient sovereignty and contributing to tackling inequalities. For instance, providing reliable, easy-to understand digital or electronic health information and patient resources or digital medical advice to persons in structurally weak regions with less access to medical care.

EU4H-2024-PJ-02-3 — Call for proposals on the development of social services for psychosocial support and rehabilitation for children and their families in paediatric oncology clinics in Member States and countries associated to the EU4Health Programme - CR-g-24-43

One of the 10 flagship initiatives of Europe's Beating Cancer Plan is to put childhood cancer under the spotlight. This can be realised through a stronger multidisciplinary cancer workforce. High-quality cancer care depends also on a high-quality workforce.

There is still a great lack of adequate psychosocial care in the field of childhood cancer in numerous European countries, including countries associated to the EU4Health Programme. Children, adolescents, and young adults with cancer require comprehensive psychosocial care, however the provisions of this care seem to vary significantly across European countries and also within countries. By 2030, it is estimated that there will be around 750 000 paediatric cancer survivors in Europe.

In developed countries, in oncology clinics and departments, a clinical oncopsychologist is one of the main actors. Together with the attending oncologist, he/she conducts therapy and orients patients towards a positive perception of the prescribed treatment.

Psycho-oncological care should be provided at all stages of the disease: during intensive treatment, rehabilitation, and, if possible, during the process of dying (terminal stage). The mental state of patients with oncological pathology is

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¹⁰ <u>eTendering - Study providing an operational concept for a European Cancer Digital. Centre</u>

characterized by a decrease in mood and activity, combined with anxiety associated with low control over the disease, its recurrent nature, and uncertainty of the prognosis. Improving the quality of life of a cancer patient is an integral part of the entire process of fighting the disease. Psycho-oncology is a relatively new branch of medical psychology. Its aim is to improve the quality of life of cancer patients. Grappling with the disease can be greatly influenced by the psychological state of the patient. Daily meetings between the patient and the psycho-oncologist, who support the patients at every stage of their treatment, have a leading place. In addition to the patients, the specialists also work with their families, as well as with the medical teams (paediatric oncologist, physiotherapist, nurse etc.).

EU4H-2024-PJ-02-4 — Call for Proposals on EU Network of Youth Cancer Survivors - CR-g-24-45

Europe's Beating Cancer Plan commits to putting childhood cancer under the spotlight and to improving the quality of life for cancer survivors. As part of the 'Helping Children with Cancer Initiative' an EU Network of Youth Cancer Survivors was launched. This EU Network is aiming to improve the quality of life of young cancer survivors through improved social networking, using the platform created by the project to strengthen the links between patients and their carers, cancer survivors, as well as social and healthcare professionals across the Union and countries associated to the EU4Health Programme.

Young individuals nominated as network representatives are to lead a collaborative approach involving diverse stakeholders to identify targeted actions and initiatives to be promoted via the network and the platform. Following a call for proposals for the EU Network under the EU4Health work programme 2021, the project EU Network of Youth Cancer Survivors ('EU-CAYAS-NET') was launched in September 2022 and is expected to be finalised in August 2024. The project OACCUs was launched in June 2022 and expected to be finalised in June 2024.

The EU-CAYAS-NET improves the quality of life of childhood, adolescent and young adult cancer survivors through improved social networking and the use of a platform to improve the links amongst patients, health professionals and other stakeholders. The network is focused on three topics which young cancer survivors have identified as a priority: quality of life; adolescent and young adult care; equality, diversity and inclusion. The network organises activities that are promoted through its platform, such as peer visits, meetings, trainings, virtual co-working, webinars, international events or policy recommendations.

OACCUs is a network promoting a healthy lifestyle through a) outdoor sports and exercise, b) psychoeducation, c) healthy nutrition, d) healthy environment (respectively sustainable lifestyle), which is achieved through interaction and exchange with peers, with people with a similar disease history, with their friends with healthcare organisations (universities, organisations for young cancer survivors, NGOs) of the participating project countries. Trained young cancer survivors, their families and friends are ambassadors and coaches in each participating country and contribute to developing and sustaining a network of youth cancer survivors.

During two workshops organised under the EU Cancer Mission, followed by the conference "Addressing the needs of young cancer survivors" on 7 February 2023, it became clear among others, that access to quality information for patients and caregivers is important in combatting cancer. Therefore, it is essential to maintain and further strengthen the EU Network of Youth Cancer Survivors and to try to make quality information in a user-friendly way available. This information should also be easily accessible online via different search engines. In addition, a communication campaign with dedicated events should also take place in different participating

Member States and associated countries to promote the EU Network of Youth Cancer Survivors.

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

EU4H-2024-PJ-02-1 — Call for Proposal to support integration of cancer images into the federated pan-European infrastructure to foster screening programmes - CR-g-24-37

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

The action will provide enabling support for cancer imaging data providers, to contribute to and benefit from the European Cancer Imaging Initiative.

The action will improve readiness of national, regional or local imaging data repositories to connect and make available their data via the Cancer Image Europe infrastructure established under the DIGITAL programme (EUCAIM project¹¹) and to use this infrastructure for data enrichment and insights by accessing the nodes, tools and methodologies offered by EUCAIM.

This action is relevant for the proposed European Health Data Space. In order to contribute to the planned EHDS, this action will seek alignment with the relevant EHDS infrastructures (MyHealth@EU and HealthData@EU). Where applicable, it will link cancer imaging databases with the relevant bodies and infrastructures in the proposed EHDS, particularly health data access bodies and HealthData@EU.

This action will also explore ways to leverage on the EHDS interoperability specifications for the European Electronic Health Record exchange Format, including relevant eHealth Network guidelines, as well as minimum specifications for datasets to be used for research and innovation.

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) and (g), of Regulation (EU) 2021/522.

This action will also support the implementation of the proposed EHDS Regulation and implement the EU4Health Programme's general objective of strengthening health systems (Article 3, point (d) of Regulation (EU) 2021/522) through the specific objective defined in Article 4, point (f), of Regulation (EU) 2021/522.

Strand (scope)

This action contributes to the implementation of the Europe's Beating Cancer Plan.

Activities that can be funded (scope)

The activities that can be funded under this action include all tasks necessary for federating data into the Cancer Image Europe platform, including creating the data warehouses and establishing processes necessary for making the imaging data and related clinical data available for secondary use. Networking, communication,

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¹¹ https://cancerimage.eu/

coordination, planning, training, reporting, and dissemination activities are also eligible.

The following activities should be addressed to:

- a) increase the geographical coverage of the European Cancer Imaging Initiative;
- b) increase the availability of cancer imaging data representative of the European population for the development of trustworthy and scalable AI-based solutions for cancer screening and care in the area of breast, lung and prostate cancers in the context of the European Cancer Imaging Initiative;
- c) increase the availability of cancer imaging data made available for research and innovation in the context of the proposed European Health Data Space;
- d) contribute to the alignment with the relevant bodies and infrastructures of the proposed European Health Data Space, particularly health data access bodies, HealthData@EU and MyHealth@EU;
- e) provide targeted and onsite support in adopting the guidelines on the best data warehouse architectures, creating the data warehouses necessary for making the data available for secondary use, establishing internal processes, training and addressing the legal issues in alignment and complementarity with the activities under the EUCAIM project and in alignment with the proposed European Health Data Space rules and infrastructures;
- f) provide support measures for quality-control, annotation and extraction of the data from the Electronic Health Records (EHRs) to the data warehouse, supporting the uptake of the European Electronic Health Record exchange Format;
- g) use and contribute to applicable minimum specifications for datasets related to cancer imaging, including data elements, controlled vocabularies, quality requirements, in alignment with the proposed European Health Data Space Regulation;
- h) increase the awareness, in cancer-related use cases, of medical images and reports specifications of the European Electronic Health Record exchange Format;
- i) provide activities to facilitate the adoption of AI-based technologies based on imaging data in the daily practice of clinical centres to support cancer screening, detection and treatment;
- j) increase access to and uptake of innovative AI-based solutions based on imaging data for cancer detection and treatment;
- k) empower patients to donate their health data through data altruism, including incentives, methods and tools for data altruism targeted at empowering patients in relation to donating their health data, in particular imaging data;
- l) increase resource efficiency of national healthcare providers through the deployment of AI-based technological solutions;
- m) contribute to other relevant actions under the Europe's Beating Cancer Plan and Cancer Mission, involving patient organisations and establishing links with data altruism organisations and regional, national or European initiatives on health data reuse for research and innovation.

The applicants should describe cancer image datasets, their expected size and level of standardisation and harmonisation with the EUCAIM agreed data requirements, the processes and tools for harmonisation and quality evaluation that will be applied to ensure reproducibility of radiomics results. The applicants should also describe how the project meets or is going to meet the minimum technical requirements elaborated in the context of the European Cancer Imaging Initiative by the EUCAIM project, including the related timeline, if applicable.

Applicants should co-ordinate with the Cancer Image Europe activities conducted by the EUCAIM project, to avoid duplication of efforts and maximise impact. The proposed action shall include a specific work package on collaboration and alignment with the EUCAIM project. The specific management, collaboration and communication mechanisms that the project will use to collaborate and integrate with EUCAIM should be described in the proposal. They may be subject to adaptations and be further detailed during the grant agreement preparation.

Applicants should take into account the developments on the European Electronic Health Record exchange Format (EEHRxF)¹² and liaise with actions and projects that are developing EEHRxF capabilities and specifications, such as the Joint Action Xt-EHR.

In order to ensure effective alignment with the European Cancer Imaging Initiative and in particular with the Cancer Image Europe platform, the following mandatory deliverables must be included:

- Every 6 months, regular report to HaDEA on progress, challenges and alignment with Cancer Image Europe, including report on data integration into the Cancer Image Europe platform;
- Sustainability report for project results and established practices, including lessons learned.

The metadata records provided to the Cancer Image Europe platform must be compliant with the EHDS metadata standard, Health DCAT-AP¹³.

Other suitable deliverables relating to project activities should be defined in the proposal.

The visual identity and communication materials of the project should be aligned with those of the Cancer Image Europe. Project website should be implemented by month 3 of the project.

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

The action will support hospitals and other imaging repositories, for example those involved in conducting cancer screening, in creating enabling conditions for becoming a node in the European federated infrastructure of cancer imaging data. Short-term improvements include strengthening the collaboration between national and regional screening programmes for breast, lung and prostate cancers, with the European Cancer Imaging Infrastructure in particular regarding the management of the screening data and opportunistic screening (as opposed to organised, population-based screening programmes) and with the relevant infrastructures of the proposed European Health Data Space, such as HealthData@EU. The project beneficiaries are expected to represent a wide range of relevant stakeholders such as researchers,

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¹² Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format (OJ L 39, 11.2.2019, p. 18)

¹³ Draft specifications are provided by the <u>HealthData@EU pilot project</u>.

NGOs, experts, Member States institutions and industry.

In the mid-term, this action is expected to increase the geographical reach of the European Cancer Imaging Initiative. It will also contribute to the alignment of the European Cancer Imaging Infrastructure with the proposed EHDS infrastructures and processes.

Close collaboration of projects participants is expected with the European Cancer Imaging Initiative, in particular the EUCAIM project, and with relevant stakeholders involved in the implementation of the proposed EHDS regulatory framework, such as the TEHDAS 2 Joint Action, QUANTUM and the HealthData@EU pilot project¹⁴. Links should be established with EU4Health actions on screening, Comprehensive Cancer Centres in Member States and other relevant actions under the Europe's Beating Cancer Plan and Cancer Mission, as well as with other relevant actions concerning the proposed EHDS. The action shall contribute to other relevant actions under the Europe's Beating Cancer Plan and the Cancer Mission.

Specific action-level indicators for reporting purposes

The applicants should consider the following indicators for reporting on the progress achieved in their project and as result of project activities:

- number of data providers who have adopted guidelines and implemented best practices relating to medical images in line with Cancer Image Europe specifications and best practices;
- number of data providers who have adopted the eHealth Network guidelines on medical imaging studies and reports;
- number of data providers who have adopted the European Electronic Health Record exchange Format (EEHRxF) for medical images;
- number of data providers who have federated data into the Cancer Imaging Europe Platform (in Tier 1, 2 and 3);
- dataset sizes and coverage (different cancer types, imaging modalities, countries) of datasets made available in the Cancer Image Europe platform;
- number of datasets listed in the metadata catalogue of Cancer Image Europe platform and compliant with the EHDS metadata standard;
- number of active users of the Cancer Image Europe platform (healthcare professionals, clinical researchers, innovators, etc.) in operational mode;
- number of training activities conducted relating to making cancer imaging data and related clinical data available for secondary use, including quality-control, annotation and extraction of the data from the Electronic Health Records (EHRs), PACS etc.;
- number of onsite visits to train and advise on best warehouse architectures, establishing internal processes, standardisation and legal issues, etc.;
- number of activities to support uptake of AI-based solutions in institutions working with cancer imaging data;
- number of AI-based solutions implemented or piloted.

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¹⁴ https://ehds2pilot.eu/results/

Other suitable indicators may be defined in the proposal. Indicators may be subject to further adjustment and specification during the grant agreement preparation with HaDEA.

Special requirements

Non-eligible activities	Purchase eligible.	of	medical	radiology	equipment	is	not

EU4H-2024-PJ-02-2 — Call for Proposals to increase health literacy for cancer prevention and care - CR-g-24-39

Objectives

The main objective of this action is to support health literacy for cancer prevention and care, to improve health literacy and to focus on reducing inequalities in cancer prevention and care.

This action supports the implementation of the Europe's Beating Cancer Plan objective to launch a project on 'Health Literacy for Cancer Prevention and Care' and 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), of Regulation (EU) 2021/522.

The action should aim to:

- improve health literacy of citizens, of patients of all ages, as well as of healthcare professionals;
- improve health literacy of citizens on cancer prevention and provide them access to adequate and reliable health information in order to empower them to make informed decisions supporting healthy lifestyles and improving health for all citizens of all ages;
- improve health literacy of patients by providing adequate, reliable, and timely information on their diagnosis and treatment to achieve their disease understanding and active involvement in the treatment; improve health literacy in palliative care;
- improve health literacy education of health professionals:
 - a. raising awareness of the impact low health literacy can have on people at risk of cancer and cancer patients;
 - b. providing healthcare professionals with health-literacy-friendly communication techniques to support their interactions with cancer patients.

Provide access to reliable, accurate and easy-to understand information to:

- a) improve access to reliable, accurate cancer information in different languages, with attention to varying digital and literacy skills and accessibility;
- improve access to reliable, accurate information on the internet, to combat misinformation available online / in social media to educate and protect citizens and patients from misinformation on the Internet and social media;
- c) support cancer literacy in relation to emotional impact and psychosocial

distress of cancer patients;

- d) build a 'Virtual library' on communication in cancer prevention and care;
- e) reduce medical jargon and improve education using plain language, easy-tounderstand written materials, including visuals to provide more culturally and linguistically appropriate health education and enhanced web-based information.

Promote health literacy, exchange of information and best practices to:

- a) introduce a cancer health literacy day to raise awareness and promote its importance;
- b) support the generation and dissemination of evidence and good practices, including at population level;
- c) gather lessons learned to enhance health literacy in general, for example, through the establishment of cancer literacy projects;
- d) get an overview of health literacy programmes developed within healthcare systems and in the community;
- e) reflect on the role of health literacy in cancer prevention and care, potential gaps, and recommendations for action;
- f) promote collaboration and exchange of information, innovations and experience on cancer health literacy between Member States and other relevant stakeholders.

Strand

This action contributes to the implementation of the Europe's Beating Cancer Plan.

Activities that can be funded (scope)

The action may include, among others, the following activities:

- a) guidelines, recommendations, lessons learned, best practices on how to increase health literacy in cancer prevention and care;
- b) information materials (e.g. manuals for patients, leaflets, websites, videos) to citizens/patients of all ages (focusing on vulnerable populations) and healthcare specialists;
- c) mapping of sources providing reliable, accurate information on the internet, in easy-to understand language;
- d) training course for healthcare specialists.

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

The expected result is the launch of projects to increase health literacy for cancer prevention and care.

This action will increase health literacy of the general population, patients, and health care specialists in the area of cancer prevention and care, will enable citizens to take informed decisions as regards prevention and screening, will help patients to take active involvement in treatment and will help health-care specialists to transmit the information in an easy-to understand way.

Specific action-level indicators for reporting purposes

The applicants will include the following specific action-level indicators and related reporting activities in their proposals:

- Number of best practices identified, collected and shared;
- Estimated number of people reached;
- Estimated number of people who indicate that the project has improved their knowledge and changed their behaviour and lifestyle;
- Number of cancer organisations and other stakeholders involved in the funded actions;
- Number of (online) materials for enhancing health literacy produced and disseminated ;
- Number of hits for web-based information;
- Number of targeted actions to specifically reach and involve vulnerable and disadvantaged population groups.

EU4H-2024-PJ-02-3 — Call for proposals on the development of social services for psychosocial support and rehabilitation for children and their families in paediatric oncology clinics in Member States and countries associated to the EU4Health Programme - CR-g-24-43

Objectives

The main objective of this action is to create a service in paediatric oncology clinics that will support children and their families during cancer treatment, by providing the necessary psychological and social support to infants, children, adolescents, and young adults from 0 months to 24 years old.

The action could support the identification of the different capabilities available across Europe and build the foundation to regularly identify gaps and needs to be addressed at national and regional level across Europe. This process will be focused on quality of life and well-being of children, adolescents, and young adults, their families, siblings, and relatives, including mental, psychosocial and nutritional support, together with clinical oncology, surgery and radiology specialities, including their nursing services.

This action supports the implementation of the Europe's Beating Cancer Plan to support childhood cancer and implements the EU4Health Programme's general objectives to strengthen health systems by improving their resilience and resource efficiency (Article 3, point (d), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, point(g), of Regulation (EU) 2021/522.

Strand (scope)

The scope of this action is to address the critical need for comprehensive psychosocial care in paediatric oncology clinics across Member States and countries associated with the EU4Health Programme. The action aims to support the establishment of a unified service system and support infrastructure to deliver psychological and social support to children, adolescents, and young adults undergoing cancer treatment, as well as their families. This includes developing organizational structures, training programs, and tools tailored to the unique needs of paediatric oncology patients. Additionally, the action will conduct a thorough assessment of existing psychosocial services across

Europe to identify best practices, gaps and opportunities for improvement. Through collaboration and knowledge sharing, the action seeks to enhance the quality of life and well-being of paediatric cancer patients and their families, ultimately contributing to the broader goals of Europe's Beating Cancer Plan and the EU4Health Programme.

Activities that can be funded (scope)

Support activities include psychological support; meeting daily activity needs; return to normal social contacts and activities inclusion, by developing communication and group work skills; utilization of free time through games; entertainment, etc.

All activities are tailored to the general state of health of the children and young people with oncological diseases. Special attention is directed to the needs and their skills, according to their age and physical capabilities.

Moreover, the aim of this action is to develop:

- a) an organisation and teams in onco-paediatric clinics;
- b) tools and training sessions as a social service for psychosocial support and rehabilitation for children and their families in paediatric oncology clinics as part of a patient treatment plan;
- c) a mapping of psychosocial services from the perspective of psychosocial health professionals working in treatment centres across Europe. In some Member States, psychosocial support is provided by the public healthcare system and in some others by cancer organisations.

Specific mandatory deliverables and/or milestones

- The mapping document should include the overarching guidelines, standards and best practices for establishing specialized teams in onco-paediatric clinics which will help to share expertise, exchange knowledge and develop common standards.
- Design and implementation of tools and training sessions for social service delivery focusing on psychosocial support and rehabilitation for children and their families in paediatric oncology clinics as integral components of patient treatment plans.
- Completion of a comprehensive mapping exercise of existing psychosocial services offered by healthcare systems and cancer organizations across Europe, conducted from the perspective of psychosocial health professionals working in treatment centers.
- Identification of capabilities, gaps, and needs at national and regional levels across Europe. Development of training programs, capacity building initiatives and tools and resources tailored to the needs of onco-paediatric clinics. Best practices sharing.
- Regular internal reporting within healthcare institutions, relevant government agencies responsible for healthcare oversight or funding (ministries of health) and professional organisations, involved in paediatric oncology care, on the quality of life and well-being outcomes for children, adolescents, and young adults undergoing cancer treatment, along with their families, siblings, and relatives, emphasizing mental, psychosocial, and nutritional support in conjunction with clinical oncology services. Findings can be disseminated to the broader healthcare community through academic publications or presentations at conferences.

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

The action will contribute to the development of a social service for psychosocial support and rehabilitation for children and their families in paediatric oncology clinics across the Union and countries associated to the EU4Health Programme. This action will address the need to establish a Europe-wide psychosocial care standard in order to ensure high-quality psychosocial care throughout the whole paediatric oncological treatment trajectory, including the transition from the paediatric to the adult care, and to eliminate inequalities in access to care.

This action will help Member States and countries associated to the EU4Health Programme to improve cooperation among their cancer services, by addressing skill gaps and better equipping the health workforce with personnel trained in cancer care.

This action will help with overcoming the consequences of the drastic separation from the usual environment, to deal with physical discomfort, late effects of treatment, low self-esteem and lack of self-confidence.

Specific action level indicators for reporting purposes

The applicants will include the following specific action-level indicators and related reporting activities in their proposals:

- Number of onco-paediatric services established or enhanced within participating institutions.
- Percentage of training sessions conducted for healthcare professionals in psychosocial support and rehabilitation services.
- Percentage of completion for the mapping exercise of existing psychosocial services across Europe.
- Number of identified gaps and needs in psychosocial support services at national and regional levels.
- Assessment of the impact on the quality of life and well-being of children, adolescents, and young adults undergoing cancer treatment, measured through standardized metrics and patient feedback.

EU4H-2024-PJ-02-4 — Call for Proposals on EU Network of Youth Cancer Survivors - CR-g-24-45

Objectives

This action supports the implementation of the Europe's Beating Cancer Plan to support childhood cancer and implements the EU4Health Programme's general objective to improve and foster health in the Union (Article 3, point (a), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a) and (g), of Regulation (EU) 2021/522.

The overall aim of maintaining the networks is to continue the collaboration between different existing stakeholder organisations and, through this network to further support social networking and further develop user friendly digital tools to easily access the information and improve the links amongst individuals, patients, children, adolescents and young adults (CAYA) cancer survivors, carers, researchers, and social and health professionals active in cancer prevention and care across the Union and countries associated to the EU4Health Programme. In addition, a healthy lifestyle promoting network could also be integrated in the mobile application and website.

Furthermore, the network will consider relapse / metastatic cancer. The network should support and provide all the necessary information related to metastatic cancer.

The network will foster social networking, peer-support, coaching, knowledge-exchange, and aims at improving:

- a) the quality of life of survivors (including mental health, education and career support, follow-up care and transition);
- b) the care for adolescents and young adults (AYA) with cancer (including metastatic cancer);
- c) Equality, Diversity and Inclusion (EDI) along the whole treatment and survivorship trajectory;
- d) promote healthy lifestyles through interaction and exchange with peers, with people with a similar disease history, with friends as well as with healthcare organisations.

Strand (scope)

This action is meant to maintain and further develop the 'EU Network of Youth Cancer Survivors' to foster social networking, peer-support, coaching, knowledge-exchange and improve the quality of life of young cancer survivors. The action is a follow-up project to the action grants EU4H-2021-PJ-04 (EU-CAYAS-NET project and OACCUs project).

Activities that can be funded (scope)

The activities funded can be as follow:

- a) Further development of the functionalities of the "EU Network of Youth Cancer Survivors" based on user needs;
- b) the utilisation and incorporation of the results from previous EU-CAYAS-NET and OACCUs projects;
- c) maintenance, update and improvement of the existent application(s) and website(s) (already created in previous EU-CAYAS-NET and OACCUs projects), and throughout these activities, the action should build up on and seek synergies with other actions funded under the EU4Health programme, such as for example the 'Cancer Survivor Smart Card' application;
- d) (further) creation of a 'virtual library', assuring access to reliable, accurate cancer information in different languages;
- e) the development of strategies for the sustainability of the app's/website's functionalities, content, and financing;
- f) the recommendation for the future and further maintenance/development of the "EU Network of Youth Cancer Survivors";
- g) Cover all EU languages;
- h) Throughout the project, wide visibility of the actions/initiatives of the EU Network will be requested.

Specific mandatory deliverables and/or milestones

Every 12 months to report on the progress of the project "EU Network of Youth Cancer Survivors".

After 18 months, in the middle of the project, to prepare a report on the sustainability, possible self-maintenance of the "EU Network of Youth Cancer Survivors" and possible synergies with other projects.

Develop a study on the impact of social networking for young cancer survivors.

Organise at least two events, meetings and/or discussions per year throughout the project.

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

The action will:

- a) improve the communication between children, adolescent, and young adult cancer survivors, formal and informal carers, and civil society;
- b) strengthen the knowledge on how to make a difference in the lives of young people with cancer and survivors;
- c) increase the knowledge and support for patients with relapse and metastatic cancer;
- d) increase the knowledge and support for patients on how to tackle the side-effects of treatments.
- e) provide resources for survivors to learn how to become an advocate to bring key messages and knowledge on cancer survivorship to main target groups (survivors, healthcare professionals, researchers, health policy makers).
- f) provide resources for survivors to pursue a healthier lifestyle, notably via sport and physical activities, healthier nutrition and mental wellbeing.

The action contributes to Europe's Beating Cancer Plan flagship initiative on paediatric cancer, which specifically mentions the EU Network of Youth Cancer Survivors as being directly linked with the activities of the "Childhood cancers and cancers in adolescents and young adults: cure more and cure better" initiative. This initiative, supported under the Horizon Europe Cancer Mission, will directly benefit from the deliverables of this action.

Specific action-level indicators for reporting purposes

The applicants will include the following specific action-level indicators and related reporting activities in their proposals:

- Estimated number of people reached;
- number of events, meetings and discussions organised;
- Estimated number of (online) materials available for the EU Network library to support the knowledge on cancer;
- Number of targeted actions to address healthier lifestyle;
- Assessment of the impact of social networking on the quality of life and well-being of young cancer survivors, measured through (patient) feedback.

3. Available budget

The estimated available call budget is **EUR 25 400 000**.

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

Topic	Topic budget	Indicative project budget	Expected number of grant agreements to be signed
Call for Proposal to support integration of cancer images into the federated pan-European infrastructure to foster screening programmes - CR-g-24-37	EUR 8 000 000	EUR 4 000 000	2
2 — Call for Proposals to increase health literacy for cancer prevention and care - CR-g-24-39	EUR 5 000 000	1 000 000	5
3 – Call for proposals on the development of social services for psychosocial support and rehabilitation for children and their families in paediatric oncology clinics in Member States and countries associated to the EU4Health Programme - CR-g-24-43	EUR 7 400 000	3 700 000	2
4 – Call for Proposals on EU Network of Youth Cancer Survivors - CR-g-24-45	EUR 5 000 000	5 000 000	1

The number of grant agreements expected to be signed is listed in the table above. 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)			
Call opening:	18 June 2024		
Deadline for submission:	10 October 2024 – 17:00:00 CET (Brussels)		
Evaluation:	October 2024 - January 2025		
Information on evaluation results:	January - February 2025		
GA signature:	June - July 2025		

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>Search Funding & Tenders</u> section). Paper submissions are NOT possible.

Proposals (including annexes and supporting documents) must be submitted using the forms provided *inside* the Submission System (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 (to be downloaded from the Portal Submission System, completed and then assembled and re-uploaded)

mandatory annexes and supporting documents (templates available to be downloaded from the Portal Submission System, completed, assembled and re-uploaded):

- -detailed budget table/calculator
- -CVs (standard) of core project team
- -list of previous projects (key projects for the last 4 years) (template available in Part B)

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 the 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**.

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

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 participants (eligible countries)

In order to be eliqible, 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 (<u>list of participating countries</u>).

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).

Specific cases

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 persons¹⁵.

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'¹⁶. 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 certain entities (e.g. entities subject to <u>EU restrictive measures</u> under Article 29 of the Treaty on the European Union

See Article 197(2)(c) EU Financial Regulation 2018/1046.

¹⁶ For the definitions, see Articles 187(2) and 197(2)(c) EU Financial Regulation 2018/1046.

(TEU) and Article 215 of the Treaty on the Functioning of the EU (TFEU)¹⁷). Such entities are not eligible to participate in any capacity, including as beneficiaries, affiliated entities, associated partners, subcontractors or recipients of financial support to third parties (if any).

Following the Council Implementing Decision (EU) 2022/2506, as of 16th December 2022, no legal commitments (including the grant agreement itself as well as subcontracts, purchase contracts, financial support to third parties etc.) can be signed with Hungarian public interest trusts established under Hungarian Act IX of 2021 or any entity they maintain. Affected entities may continue to apply to calls for proposals. However, in case the Council measures are not lifted, such entities are not eligible to participate in any funded role (beneficiaries, affiliated entities, subcontractors, recipients of financial support to third parties). In this case, co-applicants will be invited to remove or replace that entity and/or to change its status into associated partner. Tasks and budget may be redistributed accordingly.

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

Consortium composition

Please refer to the specific Consortium composition conditions in each Topic description and to the table below:

Topic	Applicants – specific eligibility criteria	Consortium composition - Specific eligibility criteria
1 — Call for Proposal to support integration of cancer images into the federated pan-European infrastructure to foster screening programmes - CR-g-24-37	Academia and education establishments, research institutes, hospitals, expert networks including ERNs, civil cociety organisations: associations, foundations, NGOs and similar entities, private entities (for profit/not for profit), Member States' authorities.	A consortium composed of at least 7 applicant organisations established in at least 7 different eligible countries.
2 — Call for Proposals to increase health literacy for cancer prevention and care - CR-g-24-39	Academia and education establishments, research institutes, hospitals, expert networks, civil society organisations: associations, foundations, NGOs, enterprises (incl. social enterprises and not for profit) in the field of public health, private entities, social media outlets press and journalist association, Member States' authorities.	Applications may be either by a single applicant or a consortium (no minimum requirement)
3 – Call for proposals on the development of social services for psychosocial support and rehabilitation for children and their families in paediatric oncology clinics in Member States and countries associated to the EU4Health Programme - CR-g-24-43	Academia and education establishments, research institutes, hospitals, expert networks, civil society organisations, associations, foundations, NGOs, private entities (for profit/not for profit); international organisations, Member States' authorities, municipalities and national	A consortium composed of at least 10 applicant organisations established in at least 5 different eligible countries.

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.

	authorities in the health domain.	
4 – Call for Proposals on EU Network of Youth Cancer Survivors - CR-g-24-45	Academia and education establishments, research institutes, hospitals, expert networks, civil society organisations, associations, foundations, NGOs and similar entities.	A consortium composed of at least 5 applicant organisations established in at least 5 different eligible countries.

Eligible activities

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

Projects should take into account the results of projects supported by other EU funding programmes. The complementarities must be described in the project proposals (Part B of the Application Form).

Projects must comply with EU policy interests and priorities (such as environment, social, security, industrial and trade policy, etc).

Financial support to third parties is not allowed.

Geographic location (target countries)

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

Duration

Topic	Expected duration of the project(s) in months
1 — EU4H-2024-PJ-02-1 - Call for Proposal to support integration of cancer images into the federated pan-European infrastructure to foster screening programmes - CR-g-24-37	36 to 48 months
2 — EU4H-2024-PJ-02-2 - Call for Proposals to increase health literacy for cancer prevention and care - CR-g-24-39	36 months
3 – EU4H-2024-PJ-02-3 - Call for proposals on the development of social services for psychosocial support and rehabilitation for children and their families in paediatric oncology clinics in Member States and countries associated to the EU4Health Programme - CR-g-24-43	36 months
4 – EU4H-2024-PJ-02-4 - Call for Proposals on EU Network of Youth Cancer Survivors - CR-g-24-45	36 months

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

Project budget

Project budgets (maximum grant amount) are listed under section 3 "available budget".

This does not however preclude the submission/selection of proposals requesting other amounts. 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 $\frac{2005/28}{536/2014}$ on investigational medicinal products for human use¹⁸ and Regulation $\frac{536/2014}{536/2014}$ on clinical trials on medicinal products for human use¹⁹).

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 these 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.

In addition for a beneficiary requesting an EU-contribution of \geq EUR 750 000 EUR an audit report produced by an approved external auditor, where it is available, and always in cases where a statutory audit is required by Union or national law, certifying the accounts for up to the last two available financial years. In all other cases, the applicant shall provide a self-declaration signed by its authorised representative certifying the validity of its accounts. 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

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).

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 participate²⁰:

- 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 misconduct²¹ (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

See Articles 136 and 141 of EU Financial Regulation 2018/1046.

Professional misconduct includes: violation of ethical standards of the profession, wrongful conduct with impact on professional credibility, false declarations/misrepresentation of information, participation in a cartel or other agreement distorting competition, violation of IPR, attempting to influence decision-making processes or obtain confidential information from public authorities to gain advantage.

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 2988/95 (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).

Applicants will also be rejected if it turns out that²²:

- 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) Projects focusing on a theme that is not otherwise covered by higher ranked projects will be considered to have the highest priority.
- 2) 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'.
- 3) 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

²² See Article 141 EU Financial Regulation <u>2018/1046</u>.

synergies between projects, or other factors related to the objectives of the call. These factors will be documented in the panel report.

4) 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.

! 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. 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:

1. Relevance:

clarity and consistency of project, objectives and planning; extent to which they match the themes and priorities and objectives of the call; contribution to the EU strategic and legislative context; European/trans-national dimension; impact/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, management, procedures, timetable, risks and risk management, monitoring and evaluation); feasibility of the project within the proposed time frame; cost effectiveness (sufficient/appropriate budget for proper implementation; best value for money) (30 points)
- Project team and cooperation arrangements: quality of the consortium and project teams; appropriate procedures and problemsolving mechanisms for cooperating within the project teams and consortium (30 points)

3. Impact: ambition and expected long-term impact of results on target groups/general public; appropriate dissemination strategy for ensuring sustainability and long-term 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 guidance 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

Additional mandatory milestones and deliverables are indicated in section 2 for each specific topic.

Form of grant, funding rate and maximum grant amount

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).

Project 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 whose GNI per inhabitant²³ is less than 90% of the EU average or
- actions with bodies from at least 14 Member States and where at least four are from Member States 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). For-profit 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

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https://hadea.ec.europa.eu/system/files/2024-

<u>01/table%20of%202024%20calculation%20of%20MSs%20GNI%20per%20inhabitant%20and%20EU%20a</u> verage%20for%20EU4Health%20AWP.pdf

- C.1 Travel and subsistence
- C.2 Equipment
- C.3 Other goods, works and services
- E. Indirect costs

Specific cost eligibility conditions for this call:

- personnel costs:
 - SME owner/natural person unit cost²⁴:Yes
- travel and subsistence unit cost²⁵: Yes
- equipment costs: depreciation
- other cost categories:
 - costs for financial support to third parties not allowed
- 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 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
 - project websites: communication costs for presenting the project on the participants' websites or social media accounts are eligible; costs for separate project websites are not eligible
 - EU Synergies call: No
 - 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.

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.

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).

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).

Please be aware that payments will be automatically lowered if 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).

Provisions concerning the project implementation

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: No
- specific rules for blending operations: No

Other specificities

n/a

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).



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 <u>create</u> an <u>EU Login user account</u>.

Once you have an EULogin account, you can <u>register your organisation</u> 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 <u>Search Funding & Tenders</u> 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 might 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
- FAQs 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 <u>IT</u> <u>Helpdesk</u>.

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).
- **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. If you would like to nonetheless benefit from different EU funding opportunities, 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 <u>AGA</u> <u>Annotated Grant Agreement</u>, <u>art 6.2.E</u>).
- **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>.