EU4Health Programme (EU4H)

Call for proposals

EU4Health-Action Grants 2023
(EU4H-2023-PJ)

Version 1.0
17 May 2022

EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HaDEA)

HaDEA.A – Health and Food
HaDEA.A.1 – EU4HEALTH I

CALL FOR PROPOSALS

Contents

0. Introduction

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

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

- Regulation 2018/1046 (EU Financial Regulation[1])
- the basic act (EU4H Programme Regulation 2021/522[2]).

The call is launched in accordance with the 2023 Work Programme[3] and will be managed by the **European Health and Digital Executive Agency, (HaDEA)** ('Agency').

The call covers the following **topics**:

- **EU4H-2023-PJ-01 — Call for proposals to support access to medical devices for cross border health threats (HERA) (CP-g-23-13)**
- **EU4H-2023-PJ-02 — Call for proposals to support stakeholders on the prevention of NCDs in the area of chronic respiratory diseases (DP-g-23-31-02)**
- **EU4H-2023-PJ-03 — Call for proposals on the prevention of NCDs in the area of mental health including actions supporting vulnerable population groups, such as migrants, refugees, Roma people and displaced people from Ukraine (DP-g-23-32-02)**
- **EU4H-2023-PJ-04 — Call for proposals on prevention of NCDs in the area of dementia and other neurological disorders (DP-g-23-33-02)**
- **EU4H-2023-PJ-05 — Call for proposals to support the implementation of the strategic agenda for medical ionising radiation applications (SAMIRA) – organisation of clinical audit campaigns as a tool to improve quality and safety of medical applications of ionising (CR-g-23-44-01)**
- **EU4H-2023-PJ-06 — Call for proposals: action grants on mental health challenges for cancer patients and survivors Sub-topic (a): Mental health and Cancer (CR-g-23-19.01)**
- **EU4H-2023-PJ-07 — Call for proposals: action grants on mental health challenges for cancer patients and survivors Sub-topic (b): European Code for Mental Health (CR-g-23-19.02)**

---

1 Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012

2 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, p.1).

3 Commission Implementing Decision C(2022) 8510 final of 21/11/2022 concerning the adoption of the work programme for 2023 and the financing decision for the implementation of the EU4Health programme.

- **EU4H-2023-PJ-08 — Call for proposals: action grants on the safety and quality of new Substances of Human Origin (Breast milk, faecal microbiota transplants) (a) HS-g-23-50.01 Breast milk (HS-g-23-50.01)**
- **EU4H-2023-PJ-09 — Call for proposals: action grants on the safety and quality of new Substances of Human Origin (Breast milk, faecal microbiota transplants) (b) HS-g-23-50.02 Faecal microbiotic transplants (HS-g-23-50.02)**
- **EU4H-2023-PJ-10 — Call for Proposals: action grants on Facilitating Organ Paired Exchange (HS-g-23-51)**
- **EU4H-2023-PJ-11 — Call for proposals for a program on orphan medical devices, in particular targeting paediatric patients (HS-g-23-65)**
- **EU4H-2023-PJ-12 — Call for proposal: action grants to contribute to the organisations of conference and events (OA-g-23-89)**

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 EU Funding & Tenders Portal Online Manual and the EU Grants AGA — Annotated Grant Agreement.

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

- the Call Document outlines the:
  - background, objectives, scope, activities that can be funded and the expected results (sections 1 and 2)
  - timetable and available budget (sections 3 and 4)
  - admissibility and eligibility conditions (including mandatory documents; sections 5 and 6)
  - criteria for financial and operational capacity and exclusion (section 7)
  - evaluation and award procedure (section 8)
  - award criteria (section 9)
  - legal and financial set-up of the Grant Agreements (section 10)
  - how to submit an application (section 11)
- the 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 AGA — Annotated Grant Agreement 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 DG SANTE website 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 re-use, 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.

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

EU4H-2023-PJ-01 — Call for proposals to support access to medical devices for cross border health threats (HERA) (CP-g-23-13)

Background and policy context

HERA is responsible for improving preparedness and response to serious cross-border threats in the area of medical countermeasures (MCM), notably by promoting advanced research and development of medical countermeasures and related technologies; and addressing market challenges and boosting the EU's open strategic autonomy in the medical countermeasures production. Medical devices and in vitro diagnostic medical devices to be used in the context of preparedness and response to cross-border health threats have a fundamental role in saving lives.

By this action, DG HERA will support and ensure the availability of healthcare solutions for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease. The use of certain medical devices, including in vitro diagnostic medical devices, encounters issues of access by patients or continuity on

the market because they are either targeted to a relatively small group of patients, or they are no longer considered advantageous to be kept on the market for commercial or other reasons. The lack of these medical devices and in vitro diagnostics can have an important impact for patients if they create a gap in the treatment, prevention or diagnosis of a cross-border health threat, particularly when there are limited or no alternatives are available in the market. Costs related to market access, in particular clinical evaluation and conformity assessment, often render the development of these devices economically not interesting. In case they are targeted to a relatively small group of patients or very specific intended purposes, innovation can lag behind comparing the advances made for other devices with wider applications.

Objectives

This action supports the policy priority to increase patients' access to medical countermeasures and it implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, and supporting innovation regarding such products (Article 3, point (c) of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (b) and (c) of Regulation (EU) 2021/522.

This action aims to support consortia that provide a platform of experienced regulatory, business planning, and device development services to help foster and guide the advancement of devices that can be used in case of serious cross-border health threats. This action does not cover orphan medical devices (medical devices for rare diseases), as these are addressed by a specific action within this work programme.

The consortia should facilitate the development, production, and distribution of these devices that can be used in case of serious cross-border health threats by providing services and advice on intellectual property, prototyping, engineering, laboratory and animal testing, grant-writing, and clinical investigation design.

A consortium should bring together different associations, organisations and/or institutions that can support medical device advancement through all stages of development: concept formation, prototyping, preclinical, clinical, manufacturing, marketing, and commercialisation.

To accomplish this work, a successful consortium should propose activities targeted to unite individuals, groups, or institutions to provide the following capabilities: knowledge of the clinical needs, business planning, conformity assessment requirements, intellectual property protections and other legal expertise, as well as scientific, engineering, pre-clinical, and clinical capabilities.

Strand (scope)

This action is part of the Crisis Preparedness strand related to improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, and supporting innovation regarding such products.

Activities that can be funded (scope)

More specifically, the project is expected to foster an innovation ecosystem by:

- promoting capacity building and knowledge sharing including by providing capabilities for promising devices.
- establishing connections between individuals and/or entities (e.g., where there is potential for knowledge sharing, joint development, etc.);

- mentoring projects through the development process;
- realistically assessing the scientific, engineering, pre-clinical and clinical innovation potential of the medical devices and adequately guide projects through the best regulatory pathway;
- supporting in finding funding/investment sources, and assessing market opportunities in order to ensure successful prototyping, development, manufacturing and marketing of promising devices;
- and providing business, legal (including intellectual property) and regulatory (and other necessary) support at the stage of submission for conformity assessment.

These activities will target medical devices and in vitro diagnostic medical devices that can be relevant for preparedness and response to cross-border health threats. Especially those that have issues to ensure access or continuity on the market and that can create a gap in the treatment, prevention or diagnosis of health threats if market access cannot be ensured. The proposals will indicate how compliance with the Medical Devices Regulation and In Vitro Diagnostic Medical Devices Regulation will be ensured. DG HERA should be included in the governance structures as appropriate.

Specific mandatory deliverables and/or milestones

Proposals under this topic must describe the specific needs of the cross-border health threats medical devices sector and show how the activities of the proposal would contribute towards addressing those needs. They should specify the challenges and bottlenecks that developers face and how the project will support them throughout the different phases of medical devices development.

In particular, the project should present a coherent plan of activities including a geographically balanced approach, which ensures equitable access to the services by developers across the EU (e.g., addressing challenges such as language barriers, diverse regulatory environments, among other).

In the proposal, consortia should lay out a fair methodology for the selection of devices that will receive support based on an open rolling application mechanism by which applications can be submitted at all times without a deadline within the lifespan of the grant. The proposals should also outline draft criteria to ensure that support is provided to the most appropriate products. Conversely, proposals are expected to outline possible challenges in reaching out and recruiting developers to participate in this project, as well as respective mitigations measures. The project should also pilot these processes with several products. The proposal should include a plan for this piloting phase including the number of products that can be expected.

Proposals should detail their unique contribution to the EU medical devices innovation ecosystem, how the project will be promoted within the EU and individual Member States, how consortia intend to use existing networks and strategies to foster networking and collaboration, and potential contribution to support the EU open strategic autonomy in the field of medical devices production.

In order to display the developments of the project, the following mandatory deliverables are foreseen:

- project workplan and implementation plan.
- Every 3 months, regular reports on challenges faced by developers and options to overcome them

- Every 3 months, regular update on the portfolio of devices requesting support
- open rolling application mechanism (including process to manage it) and methodology for the selection of products and piloting of activities with several products
- digital marketing materials of the project
- sustainability report including lessons learned on results of piloting and testing the project

In order to demonstrate progress throughout the project, the visual identity and website as well as the open rolling application mechanism are expected to be implemented in the first six months of the project.

Information and knowledge sharing is mandatory to adhere to national/regional/European/other legislation; notably, GDPR compliance is required. Proposals should include how confidential, sensitive or protective data will be exchanged and which standards will be complied with regard to the sharing of data, if applicable.

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

This action is expected to result in an increased access to medical devices and in vitro diagnostic devices that are intended to treat, prevent or diagnose in relation to a cross-border health threat. The knowledge and information gathered through this action will also provide information on market gaps and recommendations on potential investments in the field of medical devices or in vitro diagnostic medical devices.

Specific action-level indicators for reporting purposes

1. Number of developers and commercial operators reached through dissemination activities.
2. Number of products supported
3. Development phase of products supported
4. Number of networking activities organised.
5. Number of new partnerships established in the context of the project.
6. Number and type of activities piloted per specific product category.

Number of new medical devices brought to the market or that have advanced in the roadmap to the market after participating in the project

Special requirements

Type of applicants targeted	Scientific societies, academia, health authorities/institutions and NGOs, possibly also including SMEs active and with expertise in the area of the action.
Specific eligibility and selection criteria applicable to the consortium composition	Proposals must be submitted by a consortium of at least 3 applicants (beneficiaries; not affiliated entities), which complies with the following conditions: minimum 3 entities from 3 different eligible countries. In order to develop and deliver the above-mentioned activities, the consortium should demonstrate that the consortium competences

	(directly or indirectly through readily available expertise, i.e. a pool of experts) comprise: • expertise on cross-border health treats, with special focus on HERA's priority threats • legal and regulatory proficiency in the field of medical devices at EU/national levels • intellectual property protection expertise • business plan design and market readiness strategies experience • pre-clinical and clinical capabilities, including proficiency in laboratory and animal testing, proficiency in clinical evaluation and practical steps for medical devices validation, including clinical trials design, and conformity assessment • scientific/technical capabilities, including applied engineering and mathematics, prototyping and overall product development • experience in funding and investment mechanisms at EU and international level, and experience with the EU-funding system, including grant-writing and grant-application, investment products, different EU programmes supporting innovation, and if possible, experience in national research and innovation programmes This need to be clearly mentioned in the proposal
Non-eligible activities	N.A.

EU4H-2023-PJ-02 — Call for proposals to support stakeholders on the prevention of NCDs in the area of chronic respiratory diseases (DP-g-23-31-02)

Background and policy context

Chronic respiratory diseases (CRDs), which are diseases of the airways and other structures of the lung, are one of the main sources of mortality and morbidity in the Union. Some of the most common are chronic obstructive pulmonary disease (COPD), asthma, occupational lung diseases and pulmonary hypertension. In addition, the interstitial lung disease, that covers a large group of chronic lung diseases that cause scarring (fibrosis) of the lungs and post-COVID Pulmonary Fibrosis, needs attention as well.

Respiratory diseases account for 8% of all deaths in the Union and 3% of all deaths are caused by COPD[4]. Mortality rates because of respiratory diseases vary not only across the Member States, but also within countries. A larger proportion of men (8.1%) than of women (6.9%) die because of respiratory diseases in the Union

[4] OECD/European Union (2020), Health at a Glance: Europe 2022: State of Health in the EU Cycle, OECD Publishing, Paris, https://doi.org/10.1787/82129230-en

(2016). About 5.7% of the adult EU population were reported to have asthma and 4.7% another medically confirmed lower respiratory disease, including COPD[5].

Many CRDs, including asthma and COPD, are treatable and to a large extent, preventable. Beside genetics, tobacco smoking, chronic exposure to air pollutants and airway allergens, occupational and environmental chemicals and dust, and frequent lower respiratory infections during childhood are the major causes of CRDs[6]. Second-hand exposure to tobacco smoke is a risk factor for CRDs, especially in the case of children and adolescents, as they are at greater risk than adults of being adversely affected by regular second-hand exposure to tobacco smoke within their home environments.

This action supports the policy objective of reducing the burden of CRDs 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, points (a) and (i), of Regulation (EU) 2021/522.

Objectives

The aim of this action is to complement the activities of the joint action "DP-g-23-31-01 'Healthier Together' EU NCD Initiative – Chronic respiratory diseases" led by the Member States, thus helping to reduce the burden of CRDs in the Union, both at personal and population level, targeting or addressing the related risk factors and their determinants, as necessary.

Strand (scope)

This action is part of the Health promotion and disease prevention strand.

Activities that can be funded (scope)

The activities will cover the prevention and management of CRDs and will complement the joint action. Activities will include implementing projects involving civil society organisations to support the Member States' authorities in the implementation of comprehensive public health policies, the development and transfer of best practices, the development of public health guidelines, the preparation and roll-out of innovative approaches, projects supporting patient pathways and the launching of projects expected to have a significant public health impact and which benefit citizens directly. These may include projects to support the Member States in meeting the objectives of the Zero Pollution Action Plan82, the Chemicals Strategy for Sustainability83 and of the Europe's Beating Cancer Plan. Activities should also include an equity dimension and aim at reducing health inequalities..

Specific mandatory deliverables and/or milestones

Activities will include implementation of projects involving civil society organisations to support the Member States' authorities in accomplishing comprehensive public health policies to address CRDs and their risk factors in the following areas:

This action shall support and complement the Member States' efforts by doing at least one of the following activities:

[5] Respiratory diseases statistics - Statistics Explained (europa.eu).

[6] Chronic respiratory diseases (who.int).

- Mapping to define needs assessment and subsequent gap analysis in the prevention of the onset and progress of CRDs, in particular chronic obstructive respiratory diseases;
- Identification, collection, sharing, and adjustment and replication of best and promising practices on preventing and managing CRDs and their risk factors (e.g. smoking, exposure to pollutants, prevention of infectious diseases), and their roll-out for implementation through population-level health promotion interventions;
- Identification, piloting and evaluation of innovative approaches to preventing and managing CRDs and their risk factors;
- Supporting patient pathways with a focus on vulnerable groups of the population, including displaced people from Ukraine;
- Development of public health guidelines intended for use by specific professional groups working in primary health care and/or hospitals and the community, or recommendations on the early detection of CRDs in the healthcare sector (e.g. on managing childhood chronic allergy and airways disease);
- Development of guidelines and recommendations for actions, policies and programmes at national level addressing CRDs and their risk factors;
- Development and implementation of complementary awareness-raising activities on CRDs and related risk factors among health professionals and/or general public (e.g. using social media, leaflets, campaigns, self-care tools), with a focus on vulnerable groups of the population, including displaced people from Ukraine;
- Development of training programmes for health professionals and key stakeholders to better manage CRDs in the primary health care and/or hospital setting.

Every proposal must include a specific work package with measures aiming at reducing health inequalities e.g. on vulnerable groups such as migrants/refugees, people living under war conditions, disadvantaged children and women, LGBTIQ, Roma, people with disabilities and others.

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

The action will implement projects on health promotion and disease prevention, and is expected to support the Member States' efforts to reduce the burden of NCDs (approximately 80% of the disease burden in Europe), in particular that related to CRDs, and to reach the Sustainable Development Goal 3, in particular target 3.4.

The expected results will include initiatives to complement the Member States' efforts in the design, planning and implementation of best practices, such as for the development of public health guidelines, patient pathways, and support for the preparation and roll-out of new policy approaches, participation in the pilot testing of innovative practices, development of support actions such as training and improving health awareness and health literacy.

Specific action-level indicators for reporting purposes

- Number of best and promising practices identified for wider implementation;
- Number of stakeholders implementing and supporting best practices;
- Number of guidelines and other documents (e.g. recommendations) developed;
- Number of awareness campaigns developed per vulnerable group of the population (displaced people from Ukraine, Roma etc…);
- Number of innovative approaches identified for piloting and testing.
- Number of training programmes organised per type of setting

Special requirements

Type of applicants targeted	Academia and educational institutions, civil society organisations supporting the priority areas (health professional associations, patient organisations, foundations, NGOs and similar entities).
Specific eligibility criteria applicable to the consortium composition	Proposals must be submitted by a consortium of at least 3 applicants (beneficiaries; not affiliated entities), which complies with the following conditions: minimum 3 entities from 3 different eligible countries.
Non-eligible activities	Purchase of health care related products

EU4H-2023-PJ-03 — Call for proposals on the prevention of NCDs in the area of mental health including actions supporting vulnerable population groups, such as migrants, refugees, Roma people and displaced people from Ukraine (DP-g-23-32-02)

Background and policy context

Mental ill-health is one of the main sources of morbidity in the Union, at a very high cost, also to social protection systems and the economy. Population mental health has been significantly affected by the pandemic and the Russian war of aggression against Ukraine, especially vulnerable groups, including refugees and displaced people from Ukraine.

Before the onset of the COVID-19 pandemic, mental health problems affected about 84 million people in the Union, amounting to one in every six citizens, at an estimated cost to health systems and social security programmes of over EUR 600 billion (more than 4% of GDP)[7,8]. There were also indications of increased risk of mental health problems among young people aged 12–24 years, especially among those living with chronic health conditions, living in rural areas, and those not in education, training or employment[9]. The COVID-19 pandemic exacerbated these already sobering data. A significant decrease in mental well-being and an increase in negative feelings, such as tension/anxiety, loneliness, and feeling downhearted and depressed, was recorded across all age groups since the summer of 2020, with mental well-being dropping significantly across all age groups in spring 2021[10]. Increased sleep dysfunction has also been observed among general populations[11]. Population groups whose mental health has been particularly affected by the pandemic include young people, people with less secure employment, and people with less education or a lower income[12]. Adversity is an established risk factor for mental health and behavioural problems[13]. Examples of such adversities include poverty, unemployment, financial instability, a low educational level, violence, homelessness, and social isolation.

[7] OECD/EU (2018), Health at a Glance: Europe 2018: State of Health in the EU Cycle, OECD Publishing, Paris. https://doi.org/10.1787/health_glance_eur-2018-en.

[8] The most common mental disorder across EU countries is anxiety disorder, followed by depressive disorder, drug and alcohol use disorder, and several severe mental illness, such as bipolar disorder and schizophrenia, see https://ec.europa.eu/health/sites/health/files/state/docs/2018_healthatglance_rep_en.pdf.

[9] Challenges and prospects in the EU: Quality of life and public services (europa.eu).

[10] Living, working and COVID-19 (Update April 2021): Mental health and trust decline across EU as pandemic enters another year (europa.eu).

[11] Bhat S, Chokroverty S. Sleep disorders and COVID-19. Sleep Med. 2022 Mar;91:253-261. doi: 10.1016/j.sleep.2021.07.021. Epub 2021 Jul 18. PMID: 34391672; PMCID: PMC8286239.

[12] OECD (2021), Health at a Glance 2021: OECD Indicators, OECD Publishing, Paris, https://doi.org/10.1787/ae3016b9-en.

[13] Mental health preparedness and response during for the COVID-19 pandemic (who.int).

Displaced and newcomer children often have educational and psychological challenges linked to their recent arrival in the country. They may have interrupted formal education, and may have arrived without their parents, family and established social networks. In addition, they may be suffering from traumatic experiences in their countries of origin and during travel, and may also face difficult conditions in reception centres. This can result in psycho-social and educational difficulties, with different degrees of severity requiring different levels of support[14]. The 'Healthier Together' EU NCD Initiative aims to promote mental health and prevent and address mental health problems and mental disorders and support people living with mental disorders. The initiative identifies possible priority areas for action that include supporting favourable conditions for mental health and increasing resilience, implementing Mental Health in All Policies[15], promoting mental health and preventing mental disorders and improving timely and equitable access to high quality services, protecting rights, enhancing social inclusion and tackling stigma associated with mental health problems.

This action supports the policy objective of promoting mental health and preventing and addressing mental health problems and disorders 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, points (a) and (i), of Regulation (EU) 2021/522.

Objectives

The aim of this action is to complement the implementation of the joint action "DP-g-23-32- 01 'Healthier Together' EU NCD Initiative – Mental Health" led by the Member States, thus helping to promote mental health, and to reduce the burden of mental health problems in the Union, both at individual and population level, targeting or addressing the related risk factors and their determinants, as necessary.

Strand (scope)

This action is part of the Health promotion and disease prevention strand.

Activities that can be funded (scope)

The activities will cover the promotion of mental health and prevention and management of mental health problems, supporting in particular persons under vulnerable circumstances/vulnerable population groups (such as migrants, refugees, Roma people and displaced people from Ukraine). The activities will run in parallel to the joint action and will include the implementation of projects involving civil society organisations to support the Member States' authorities in implementing comprehensive public health policies in the area of mental health, the development and transfer of best practices, the development of public health guidelines, the preparation and roll-out of innovative approaches and projects supporting patient pathways, and launching of targeted projects to support vulnerable groups including migrants, refugees, Roma people and displaced persons from Ukraine.

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

Specific mandatory deliverables and/or milestones

[14] Commission presents key principles and practices for supporting the inclusion of displaced children from Ukraine in school education | European Education Area (europa.eu); Register of Commission Documents - SWD(2022)185 (europa.eu).
[15] Mental health in all policies (europa.eu).

The activities under this action shall support and complement the Member States' efforts in developing and implementing a comprehensive and prevention-oriented approach to mental health.

The activities shall address vulnerable and socio-economically disadvantaged population groups whose mental health has been disproportionately affected by the pandemic, including the elderly, young people, people with less secure employment, and people with less education or a lower income and particularly migrants, refugees, Roma people, displaced people from Ukraine as well as people still living in Ukraine.

Activities will also take into consideration socio-economic and environmental determinants as established risk factors for mental health and behavioural problems (e.g. poverty, unemployment, financial instability, a low educational level, violence, air pollution and climate crisis, homelessness, and social isolation).

The activities shall support the implementation of a comprehensive and prevention-oriented approach to mental health and support the actions in the Commission Communication on a comprehensive approach to mental health, including:

1. Promotion of good mental health and prevention of mental health problems through **implementation of best and promising practices and approaches and implementable research results**;

2. Design and implementation of a mental health in all policies **coordinated approach** between public authorities in multiple ministries and other relevant stakeholders;

3. Development of tools and approaches for mental health literacy and awareness-raising, **early detection** of those at risk for developing mental health problems within specific community settings, such as schools, elderly care centres, migrants/refugee centres and prisons, taking into account specific needs of the **vulnerable groups** of the population;

4. **Improving access** to evidence-based and innovative, promising and personalised approaches and interventions in the management of mental health problems, including improving community-based care and approaches, use of self-management tools and social prescribing for better outcomes;

5. Creating favourable conditions for patients, their families and (in)formal carers to improve their **quality of life**, with a focus on breaking through **stigma**.

Reducing health inequalities in mental health within vulnerable groups should be addressed horizontally in all activities. To ensure a coherent approach and complementarity, it is key that this action builds on past and ongoing projects such as joint actions (e.g. JA ImpleMENTAL), relevant projects with WHO and OECD and stakeholders, and other EU funded initiatives on mental health.

This action shall support and complement the Member State's efforts in addressing mental health challenges and in implementing a comprehensive approach to mental health, by doing at least one of the following activities:

- Identification, collection, and sharing and adjustment and replication of best and promising practices on a comprehensive approach to mental health

for vulnerable populations, and their roll-out for implementation through population-level health promotion interventions;

- Development of public health guidelines or documents intended for use by specific professional groups working with vulnerable groups with a potential need to address mental health challenges (e.g. first aid providers, social care workers);
- Identification, piloting and evaluation of innovative approaches to preventing and managing mental health problems in various community settings e.g. use of social prescribing (arts, sports etc.) and use of a community-based social franchising approach[16];
- Development of guidelines and recommendations for actions, policies and programmes at national level catering to the specific needs of vulnerable populations e.g. suicide prevention programmes and programmes supporting the transition from youth to adult care;
- Development of a code of good practice on how the people with 'lived experience' can be integrated in the development of mental health policies and programmes;
- Development and implementation of awareness-raising activities with a focus on breaking down stigma on mental health (such as prevention of suicide and depression) with a focus on vulnerable groups;
- Development, piloting and possible implementation of a methodology to ensure that mental health is integrated in relevant policies (Mental Health in All Policies approach);

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

The action will implement projects on health promotion and disease prevention, taking into account relevant results of Horizon 2020[17] and Horizon Europe projects, and is expected to support the Member States' efforts to reduce the burden of NCDs (approximately 80% of the disease burden in Europe), in particular that related to mental health problems, and to reach the Sustainable Development Goal 3, in particular target 3.4.

The expected results will include initiatives to complement the Member States' efforts in the design, planning and implementation of best practices, such as for the development of public health guidelines, supporting patient pathways, and support for the preparation and roll-out of new policy approaches, participation in the pilot testing of innovative practices, development of support actions such as training and improving health awareness and health literacy.

Specific action-level indicators for reporting purposes

- Number of best practices identified for wider implementation;
- Number of Member States implementing best practices;
- Number of guidelines and other documents (e.g. recommendations, codes of good practice) developed;
- Number of awareness campaigns developed per vulnerable group of the population (children, young people, elderly, Roma etc.);
- Number of innovative approaches identified
- Number of innovative approaches piloted

[16] 'ABCs of Mental Health'

[17] CORDIS | European Commission (europa.eu), e.g. RefugeesWellSchool (https://cordis.europa.eu/project/id/754849).

Special requirements

Type of applicants targeted	Academia and educational institutions, civil society organisations supporting the priority areas (health professional associations, patient organisations, foundations, NGOs and similar entities).
Specific eligibility criteria applicable to the consortium composition	Proposals must be submitted by a consortium of at least 3 applicants (beneficiaries; not affiliated entities), which complies with the following conditions: - Minimum 3 entities from 3 different eligible countries; - At least one NGO working in the field of mental health; - At least one patient organisation working in the field of mental health; This needs to be clearly highlighted in the proposal
Non-eligible activities	N.A.

EU4H-2023-PJ-04 — Call for proposals on prevention of NCDs in the area of dementia and other neurological disorders (DP-g-23-33-02)

Background and policy context

Neurological disorders (including dementia) are among the main sources of morbidity in the Union.

Neurological disorders are conditions characterised as being in or associated with the central or peripheral nervous system. Major non-communicable neurological disorders are Alzheimer's disease, which is the main cause of dementia, and other forms of dementia, cerebrovascular diseases including stroke, Parkinson's disease, multiple sclerosis, epilepsy, various headache disorders among which migraine, and traumatic brain injuries. Many more – both communicable and non-communicable – neurological disorders exist, often also with a substantial disease burden and premature mortality. These latter diseases are addressed in Union programmes and actions on rare diseases. Neurological disorders are the leading cause of disease burden in terms of Disability-Adjusted Life Years (DALYs) and second leading cause of deaths (2016). The four largest contributors of neurological DALYs in 2016 were stroke (42%), migraine (16%), Alzheimer's disease and other dementias (10%), and meningitis (8%), the latter not being an NCD. As the prevalence of the major disabling neurological disorders steeply increases with age, there will be an increasing demand for treatment, rehabilitation and support services for neurological disorders in the coming years in all countries with ageing populations.

The 'Healthier Together' EU NCD Initiative has identified possible priority areas for action on neurological disorders, that include implementing national plans for stroke, changing attitudes towards dementia, and tackling stigma associated with dementia, prevention and early detection of neurological diseases, in particular Alzheimer's disease and dementia, and implementing person-centred integrated care models.

This action supports the policy objective of reducing the burden of dementia and other neurological disorders, 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, points (a) and (i), of Regulation (EU) 2021/522.Examples of such adversities include poverty, unemployment, financial instability, a low educational level, violence, homelessness, and social isolation.

Objectives

The aim of this action is to complement the implementation of the joint action "DP-g-23-33- 01 'Healthier Together' EU NCD Initiative – Dementia and neurological disorders" led by the Member States, thus helping to reduce the burden of dementia and other neurological disorders in the Union, both at personal and population level, targeting or addressing the related risk factors and their determinants, as necessary.

Strand (scope)

This action is part of the Health promotion and disease prevention strand.

Activities that can be funded (scope)

The activities will cover the prevention and care of dementia and other neurological disorders, taking into account relevant results of Horizon 2020 projects[94], and of relevant Horizon Europe projects, and will run in parallel to the joint action. Activities will include the implementation of projects involving civil society organisations to support the Member States' authorities in implementing comprehensive public health policies, the development and transfer of best practices, the development of public health guidelines, the preparation and roll-out of innovative approaches and projects supporting patient pathway, and launching of projects, such as on training, health awareness and health literacy, that are expected to have a significant public health impact. Activities should also include an equity dimension and aim at reducing health inequalities.

Specific mandatory deliverables and/or milestones

This action shall support and complement the Member States' efforts by doing at least one of the following activities:

- Mapping to define needs assessment and subsequent gap analysis in the prevention of dementia and other neurological disorders, such as cerebrovascular diseases (e.g. stroke), Parkinson's disease, multiple sclerosis, epilepsy and headache disorders;
- Identification, collection, sharing, adjustment, and replication of best and promising practices on preventing and managing dementia and other neurological disorders and their risk factors (e.g. smoking, poor diet, low levels of physical activity), as well as their roll-out for implementation through population-level health promotion interventions;
- Identification, piloting and evaluation of innovative approaches on preventing and managing dementia and other neurological disorders;
- Development of public health guidelines or recommendations on improved monitoring and screening for dementia and other neurological disorders such as stroke, through the community and/or primary care;
- Development of guidelines and recommendations to better manage dementia and neurological disorders through the implementation of person-centred integrated care models;

- Development of guidelines and recommendations for actions, policies and programmes at national level in addressing dementia and other neurological disorders;
- Development and implementation of complementary awareness-raising activities on dementia and other neurological disorders and their risk factors, with a focus on vulnerable populations, such as displaced people from Ukraine.

Every proposal must include a specific work package with measures aiming at reducing health inequalities, including approaches addressing, for example, vulnerable groups such as migrants/refugees, people living under war conditions, disadvantaged children and women, LGBTIQ, Roma, people with disabilities and others'.

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

The action will implement activities on health promotion and disease prevention and is expected to support the Member States' efforts to reduce the burden of non-communicable diseases (approximately 80% of the disease burden in Europe), in particular that related to dementia and other neurological disorders, and to reach the Sustainable Development Goal 3, in particular target 3.4.

The expected results will include initiatives to complement the Member States' efforts in the design, planning and implementation of best practices, such as for the development of public health guidelines, supporting patient pathways, and support for the preparation and roll-out of new policy approaches, participation in the pilot testing of innovative practices, development of support actions such as training and improving health awareness and health literacy.

Specific action-level indicators for reporting purposes

- Number of best and promising practices identified for wider implementation;
- Number of best practices transferred;
- Number of stakeholders implementing and supporting best practices;
- Number of guidelines and other documents (e.g. recommendations) developed;
- Number of awareness campaigns developed per vulnerable group of the population (displaced people from Ukraine, Roma etc.);
- Number of innovative approaches identified for piloting and testing;
- Number of innovative approaches piloted.

Special requirements

Type of applicants targeted	Academia and educational institutions, civil society organisations supporting the priority areas (health professional associations, patient organisations, foundations, NGOs and similar entities).
Specific eligibility criteria applicable to the consortium composition	Proposals must be submitted by a consortium of at least 3 applicants (beneficiaries; not affiliated entities), which complies with the following conditions: - Minimum 3 entities from 3 different eligible countries;
Non-eligible activities	Purchase of health care related products

EU4H-2023-PJ-05 — Call for proposals to support the implementation of the strategic agenda for medical ionising radiation applications (SAMIRA[18]) – organisation of clinical audit campaigns as a tool to improve quality and safety of medical applications of ionising radiation (CR-g-23-44-01)

Background and policy context

A variety of nuclear and radiation technologies play a key role in the fight against cancer. Mammography, computed tomography and other forms of radiological imaging are indispensable technologies for all stages of cancer management. Radiotherapy is among the most effective, efficient and widely used cancer treatments available to patients and physicians. Nuclear medicine (e.g. radiopharmaceutical treatments and diagnostics) is routinely used for cancer diagnosis and follow-up, and increasingly available for cancer treatment.

The Euratom Treaty[19] defines a key EU competence for health and safety with respect to ionising radiation, and the Union has established an ambitious legislative framework for protecting patients, volunteers in medical research and medical staff from the undesirable effects of this radiation. The Euratom Basic Safety Standards (BSS) Directive[20] introduces requirements, such as those for justification of individual patient exposures, quality assurance and clinical audit, which are applicable to all kinds of medical practice involving ionising radiation.

In February 2021, the Commission adopted the SAMIRA action plan, which sets out a series of actions to advance the quality and safety of medical procedures involving ionising radiation, with the aim of bringing tangible benefits to patients by ensuring that these procedures are used strictly in line with clinical needs and with the highest standards of quality and safety. These actions provide an important contribution to the Europe's Beating Cancer Plan objectives of ensuring sustainable cancer prevention, supporting the early detection of cancer and ensuring access to high standards of diagnosis and treatment. The SAMIRA action plan also contributes to support the implementation of the BSS Directive in particularly challenging areas, for example those requiring changes in the organisation and resource allocation in healthcare, such as clinical audit. Past studies and more recent work from the Commission showed that the clinical audit practice in the Member States differs considerably.

To improve the situation, in 2019, the Commission launched the QuADRANT project whose objective was to promote constant improvement in quality and safety of radiology, radiotherapy and nuclear medicine through the implementation of clinical audit. The project resulted in a report identifying good practices in Member States and available guidance and resources for clinical audits, at national, European and international level and providing further guidance and recommendations on improving the implementation and integration of clinical audits into national healthcare systems. Additionally, the EU-JUST-CT project, which started in April 2021 and runs until March 2024, is conducting pilot audits of justification of computed tomography procedures in several Member States following a common methodology.

[18] SAMIRA: Strategic Agenda for Medical Ionising Radiation Applications (europa.eu).

[19] The Euratom Research and Training Programme covers nuclear research and innovation - Euratom Research and Training Programme (europa.eu).

[20] Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directive 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ, L 013 17.1.2014, p.1).

'The Steering Group on Quality and Safety (SGQS) created by the Commission under the SAMIRA initiative identified this topic as a priority area of work, and a working group has been created to define further actions for improving the implementation of clinical audit in Member States' health systems.

Objectives

This action will contribute to the implementation of the Europe's Beating Cancer Plan and supports the policy objective of ensuring access to high standards in cancer diagnosis and treatment, 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, points (a) and (g), of Regulation (EU) 2021/522.

The objective of this action is to pilot clinical audit campaigns in Member States in diagnostic and interventional radiology, radiotherapy and nuclear medicine by identifying and bringing together relevant actors and resources. It should take into account the specificities of the national health systems.

Up to four proposals of different sizes will be accepted, ranging from organising pilot audits in a single (large) department or hospital, a hospital trust, a region or a single Member State to coordinated audits in several Member States and should be implemented in coordination with the appropriate health authorities. A priority will be given to proposals covering several types of medical practice in several Member States and also to different practices within different regions of a Member State. Proposals should include considerations and activities to scale up pilot outcomes into the broader health system practice of Member State(s).

It should build on the results of the QuADRANT and the EU-JUST-CT project. In particular, the clinical audit action should seek to improve justification of radiological imaging, in line with the 2015 Council conclusions on this topic ([21]), and the implementation of the optimisation principle.

The action will be implemented in close cooperation with other SAMIRA activities[22] on quality and safety of medical applications of ionising radiation and include a reporting on the pilots carried out in Member States to the Steering Group for Quality and Safety (SGQS).

Strand (scope)

This action is part of the Cancer Strand.

Activities that can be funded (scope)

This activity targets actors and activities related to quality and safety of medical applications of ionising radiation, based on the relevant requirements of Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.

([21]) Council conclusions on the justification of medical imaging involving exposure to ionising radiation, adopted by the Council at its 3433rd meeting held on 3 December 2015 (http://data.consilium.europa.eu/doc/document/ST-14617-2015-INIT/en/pdf)

[22] See SAMIRA Webpage: https://energy.ec.europa.eu/topics/nuclear-energy/radiological-and-nuclear-technology-health/samira-action-plan_en

Specific mandatory deliverables and/or milestones

The activities that can be funded under this project include networking, communication, coordination, planning, recruiting, training, auditing, reporting and dissemination activities.

This also includes the identification of the documentation needed to implement clinical audits in the different medical specialties using ionising radiation, such as clinical audit guidelines, audit templates and agreed standards for good medical practice. The elaboration of new guidance, templates or standards could also be covered, especially in areas of underdeveloped clinical audit practice, such as nuclear medicine. Document, resources, and best practices identified and / or developed in the QuADRANT[23] study and the EU-JUST-CT study should serve as a basis for this part of the project activities.

It finally includes the development and / or use of appropriate web-based tools to share clinical audit guidance, manuals, templates and agreed clinical standards, as well as best practices and audit results. In particular, the use of the EU Health Policy Platform should be considered to share resources, knowledge and best practices and to boost discussions about clinical audit.

1) Provide updated plannings of the clinical audit campaigns (min. every six months) including:

- participating hospitals/departments
- audited medical procedures
- agreed standards to be used as the basis for clinical audit
- auditors (name, organisation)

2) Share the auditors training materials

3) Develop guidance and standards within the project

4) Develop general reports of the campaigns including recommendations on how to better embed clinical audit practice in the broad health system of the participating Member States

5) Develop web-based tool(s) to share relevant resources and results

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

The action will contribute to a better implementation of the BSS Directive's requirement with regard to clinical audit taking into account the differing challenges across Member States. It can serve as a reference action to establish a permanent clinical audit mechanism in some Member States.

It will improve the overall quality and safety of radiological medical procedures in order to bring their full benefits to patients. It will contribute to the development of

[23] European Commission, Directorate-General for Energy, Radiation Protection series No 198, Howlett, D., Giammarile, F., Jornet, N., et al., Current status and recommendations for improving uptake and implementation of clinical audit of medical radiological procedures : QuADRANT, a European study on clinical audit of medical radiological procedures, Publications Office of the European Union, 2023, https://data.europa.eu/doi/10.2833/468186

the professional skills of the auditors and of the audited professionals and foster inter-disciplinary and multi-professional relationships. It should contribute to the development of leadership in this area.

This action could also strengthen structures involved in hospital accreditation or individuals involved in professional healthcare certification schemes.

The pilot outcomes should be relevant to health systems as a whole and be designed in a way that their outcomes can be scaled up into the broader health system practice of the Member State(s).

Specific action-level indicators for reporting purposes

- Number of participating Member States
- Number of participating hospitals/departments
- Number of clinical audits carried out
- Number of auditors trained
- Number of new guidance or standards developed
- Number of clinical audit resources shared through the web-based tool(s)

Special requirements

Type of applicants targeted	Academia (e.g. public health institutes) and education establishments, research institutes, hospitals, professional societies, competent authorities and established networks in the field pf public health.
Specific eligibility and selection criteria applicable to the consortium composition	Applications may be submitted either by a single applicant or a consortium. In both cases (single applicants or consortium) the proposal must include one eligible applicant with expertise in at least one of the following medical specialties: radiology, radiotherapy, nuclear medicine, other medical specialties using ionising radiation. This needs to be clearly highlighted in the proposal.
Non-eligible activities	N.A.
Other topic requirements	A priority will be given to proposals covering several types of medical practice in several Member States or different practices within different regions of a Member State. Proposals should include considerations and activities to scale up pilot outcomes into the broader health system practice of Member State(s).

EU4H-2023-PJ-06 — Call for proposals: action grants on mental health challenges for cancer patients and survivors Sub-topic (a): Mental health and Cancer (CR-g-23-19.01)

Background and policy context

Every year around 2.7 million people living in the Union are diagnosed with cancer and the number of cancer survivors is growing every year with a continuous increase in 5-year survival rates for the most common cancer types in all countries. These improvements are driven by a number of factors, including effective prevention and screening programmes as well as advances in diagnostics and surgical techniques. The number of childhood cancer survivors is also expected to rise substantially in the years to come. While this is a reason for optimism, survivors, their families and carers can experience significant challenges. These challenges could often be avoided or mitigated by cooperation between health and social care systems, and as well as cooperation with employers. In this context, the focus should no longer be on 'how long' people live after diagnosis, but rather on 'how well and how long' they live. Europe's Beating Cancer Plan and the EU Mission on Cancer aim not only to ensure that cancer patients survive their illness, but that they live long, fulfilling lives, free rom discrimination and unfair obstacles. Cancer survivors face a number of common issues including unmet psychosocial needs, and issues related to rehabilitation, emotional distress, secondary cancers and tumour recurrence, including metastatic disease.

Up to 30% of children affected by cancer suffer severe long-term consequences. As the number of childhood cancer survivors continues to grow, comprehensive care, treatment and follow-up are essential to help young patients make a good recovery and enjoy an optimal quality of life. The new 'Cancer Survivor Smart-Card' will address the specificities of childhood cancer survivors, including psychological support. In addition, the EU Network of Youth Cancer Survivors[24] was launched in February 2022 to support the European Year of Youth. It will connect young cancer survivors and strengthen long-term follow-up in cancer care plans at national and regional level focusing also on mental health and psychosocial care.

There is a need to inform people about evidence-based actions they can take for themselves or their families to promote mental health and to reduce the risk of mental health problems. A European Code for Mental Health, based on the approach for the European Code against Cancer[25], would help Member States and public health authorities in their efforts to promote mental health amongst their citizens.

This action will support the policy objective of reducing the burden of cancer and of mental health problems 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, points (a), (b) and (i), of Regulation (EU) 2021/522).

Objectives

This action aims to address mental health challenges in cancer patients and survivors, and their carers[26] and families

Strand (scope)

[24] Funding & tenders (europa.eu) - EU Network of Youth Cancer Survivors (EU-CAYAS-NET); OAC Connects Us.

[25] European Code Against Cancer - International Agency for Research on Cancer (IARC). European Commission: 12 ways to reduce your cancer risk.

[26] This includes family members, relatives and friends and excludes health professionals.

This action is part of the Health promotion and disease prevention strand and Cancer as cross-cutting.

Activities that can be funded (scope)

Activities will include:

(i) systematic screening of the mental health status of cancer patients, their carers and families in order to identify persons at risk of developing mental health problems;

(ii) development of methodologies that can support the identification of patients, their carers and families, with risk factors for mental health challenges, and the piloting and further testing of such methodologies to assess their impact and transferability at EU level;

(iii) providing psychological and psychosocial support and targeted interventions for cancer patients, survivors, their carers and families in order to prevent long-term mental health consequences;

(iv) developing guidance and recommendations for professionals to ensure mental health aspects throughout the entire patient care pathway;

(v) provision of professional psychosocial support for children, adolescents and young adults with cancer.

Specific mandatory deliverables and/or milestones

This action aims to address mental health challenges in cancer patients and survivors, their families and informal carers[27] and improve their quality of care and life by screening and identifying at risk individuals for mental health challenges, providing psychosocial support and developing guidelines to incorporate mental health care throughout the duration of the cancer pathway

Mental health care activities may include innovative and promising approaches (such as social prescription, role of sport and physical activity, healthy lifestyle) and should focus on vulnerable groups like children, young people and elderly.

Activities shall include one or more of the following:

- development and piloting of methodologies on identifying cancer patients/survivors, their families and informal carers, with risk factors for mental health challenges, including testing, adjustment, and replication of these methodologies at EU-level;
- development of a set of practical documents (e.g. guidelines, recommendations) to guide and support health professionals (e.g. working in primary cancer care and/or hospitals), to support mental health inclusion in the entirety of the patient cancer care pathway;
- Development of a standard approach for systematic screening of mental health challenges in cancer patient/survivors, their families and informal carers, with a special focus on children, young people and the elderly.

[27] This includes family members, relatives and friends and excludes health professionals

Every proposal must include a specific work package with measures aiming at reducing health inequalities and look specifically at the role of innovative and promising approaches.

These activities shall contribute to improved prevention of mental health challenges, better and earlier detection of individuals at risk of developing mental health challenges and improved quality of life and care of patients/survivors, their families and informal carers.

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

The expected results include the provision of psychological and psychosocial support to cancer patients/survivors, their families and informal carers and a series of targeted interventions. This action will contribute to reducing the risk of long-term mental health problems among cancer patients and survivors, as well as their careers and families.

Specific action-level indicators for reporting purposes

- Number of Member States developing and piloting relevant methodologies;
- Number of relevant methodologies produced
- Number of relevant methodologies tested;
- Number of guidelines, technical papers, protocols delivered;
- Number of individuals receiving psychosocial support by gender and by age group i.e. 9 or younger, 10-15; 15-24; 25-49; 50-64; 65 and above.
- Number of individuals receiving psychosocial support by status i.e. cancer patients/survivors, carers, family members;
- Satisfaction rate of individuals receiving psychosocial support by social status, gender and age.

Special requirements

Type of applicants targeted	Civil society organisations (professional associations, patient organisations, foundations, NGOs and similar entities) with expertise in the field of mental health and cancer, academia and education establishments, research institutes, expert networks and established networks in the field of public health, and Member States' authorities
Specific eligibility criteria applicable to the consortium composition	Proposals must be submitted by a consortium of at least 3 applicants (beneficiaries; not affiliated entities), which complies with the following conditions: - Minimum 3 entities from 3 different eligible countries; - At least one NGO working in the field of cancer or mental health; - At least one patient organisation working in the field of cancer or mental health; This needs to be clearly mentioned in the proposal

Non-eligible activities	Purchase of health care related products.

EU4H-2023-PJ-07 — Call for proposals: action grants on mental health challenges for cancer patients and survivors Sub-topic (b): European Code for Mental Health (CR-g-23-19.02)

Background and policy context

Every year around 2.7 million people living in the Union are diagnosed with cancer and the number of cancer survivors is growing every year with a continuous increase in 5-year survival rates for the most common cancer types in all countries. These improvements are driven by a number of factors, including effective prevention and screening programmes as well as advances in diagnostics and surgical techniques. The number of childhood cancer survivors is also expected to rise substantially in the years to come. While this is a reason for optimism, survivors, their families and carers can experience significant challenges. These challenges could often be avoided or mitigated by cooperation between health and social care systems, and as well as cooperation with employers. In this context, the focus should no longer be on 'how long' people live after diagnosis, but rather on 'how well and how long' they live. Europe's Beating Cancer Plan and the EU Mission on Cancer aim not only to ensure that cancer patients survive their illness, but that they live long, fulfilling lives, free from discrimination and unfair obstacles. Cancer survivors face a number of common issues including unmet psychosocial needs, and issues related to rehabilitation, emotional distress, secondary cancers and tumour recurrence, including metastatic disease.

Up to 30% of children affected by cancer suffer severe long-term consequences. As the number of childhood cancer survivors continues to grow, comprehensive care, treatment and follow-up are essential to help young patients make a good recovery and enjoy an optimal quality of life. The new 'Cancer Survivor Smart-Card' will address the specificities of childhood cancer survivors, including psychological support. In addition, the EU Network of Youth Cancer Survivors[28] was launched in February 2022 to support the European Year of Youth. It will connect young cancer survivors and strengthen long-term follow-up in cancer care plans at national and regional level focusing also on mental health and psychosocial care.

There is a need to inform people about evidence-based actions they can take for themselves or their families to promote mental health and to reduce the risk of mental health problems. A European Code for Mental Health, based on the approach for the European Code against Cancer29, would help Member States and public health authorities in their efforts to promote mental health amongst their citizens.

This action will support the policy objective of reducing the burden of cancer and of mental health problems 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, points (a), (b) and (i), of Regulation (EU) 2021/522).

Objectives

[28] Funding & tenders (europa.eu) - EU Network of Youth Cancer Survivors (EU-CAYAS-NET); OAC Connects Us.

[29] European Code Against Cancer - International Agency for Research on Cancer (IARC). European Commission: 12 ways to reduce your cancer risk.

This action aims to address mental health challenges in cancer patients and survivors, and their carers[102] and families.

Strand (scope)

This action is part of the Health promotion and disease prevention strand.

Activities that can be funded (scope)

Activities will include: (i) Development of a European Code for Mental Health which contains messages that are evidence-based, easy-to-understand and easy-to-implement for citizens about actions they can take for themselves or their families to reduce their risk of mental health problems[103].

Specific mandatory deliverables and/or milestones

This action aims to address mental health challenges in European citizens through easy-to-understand messages that most people can follow without any special skills or advice. Through easy wording that explains the mental health risk, each of the recommendations in the code will support people in how they can protect themselves, their families and their carers[30], and improve their quality of care and life.

This action will support the promotion of good mental health and prevention of mental health problems, in the general population, through the development of a European Code for Mental Health. The objective of a European Code for Mental Health will be to inform EU citizens about evidence-based actions they can take for themselves or their families to promote mental health and to reduce the risk of mental health problems, thereby contributing to increasing the mental health resilience of societies.

The creation of the European Code for Mental Health shall follow the example of the European Code against Cancer, by identifying actions, based on generally accepted scientific evidence, that individual citizens can take to help prevent mental health issues.

Efforts shall be made to include a multidisciplinary approach in identifying, analysing and reviewing scientific evidence.

The European Code for Mental Health shall:

- be presented as an IT on-line toolbox to be easily available and accessible to all EU citizens (general population) in all the EU official languages[31] and Ukrainian;
- be understandable and easily applicable by the general public;
- raise awareness amongst the general population of the importance of mental health in our daily lives;
- recognise that individual choices are heavily framed by social, economic and commercial determinants of health.
- increase knowledge on the prevention of mental health problems, including recognising early signs and symptoms;

[30] This includes family members, relatives and friends and excludes health professionals

[31] 24 official languages of the EU: Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Irish, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish.

- empower citizens to take action to improve their own mental health and that of their families and friends, while recognising that their choices and paths are framed by their environments ;
- help to break through stigma and discrimination related to mental health, promoting empowerment without placing undue burden on individuals by suggesting that they are solely responsible for their mental health outcomes but rather considering how broad health, social and commercial determinants can impact mental health;
- provide information on how to seek help or mental health support.

The activities shall include:

- consultation in an interdisciplinary approach including public health and mental health specialists (e.g. public health doctors, psychiatrists, psychologists, nurses) in at least 5 Member States (at least 3 specialists in different fields in each Member State) on the content and usability of the draft European Code for Mental Health before pilot-testing;
- pilot-testing of the draft European Code for Mental Health amongst a sample that is representative of the general public in at least 5 Member States, to ensure that the messages are easy to understand and easily applicable in an individual's daily life;
- adjustment of the European Code for Mental Health based on the outcomes of the consultation and pilot-testing.

In order to ensure sustainability, the online toolbox shall be available to be embedded in the DG SANTE official website, at the end of the project.

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

The development of a European Code for Mental Health will empower citizens, help raise awareness and improve their own health literacy.

Specific action-level indicators for reporting purposes

- Number of evidence-based recommendations identified, based on an interdisciplinary approach;
- Number of public health specialists consulted per Member State;
- Number of mental health specialists consulted per Member State;
- Number of pilot-tests carried out ;
- Number of Member States covered by pilot-tests;
- Satisfaction rate of target audience in pilot-tests.

Special requirements

Type of applicants targeted	Civil society organisations (professional associations, foundations, NGOs and similar entities) with expertise in the field of mental health, academia and education establishments, research institutes, expert networks and established networks in the field of public health, and Member States' authorities
Specific eligibility criteria applicable to the consortium composition	Proposals must be submitted by a consortium which complies with the following conditions:

	- Minimum 5 entities (beneficiaries, not affiliated entities) from 5 different eligible countries; - At least one NGO working in the field of mental health; - At least one patient organisation working in the field of mental health; - At least one public authority responsible for mental health This needs to be clearly mentioned in the proposal
Non-eligible activities	Purchase of health care related products.

EU4H-2023-PJ-08 — Call for proposals: action grants on the safety and quality of new Substances of Human Origin (Breast milk, faecal microbiota transplants) (a) HS-g-23-50.01 Breast milk (HS-g-23-50.01)

And

EU4H-2023-PJ-09 — Call for proposals: action grants on the safety and quality of new Substances of Human Origin (Breast milk, faecal microbiota transplants) (b) HS-g-23-50.02 Faecal microbiotic transplants (HS-g-23-50.02)

Background and policy context

The 2019 evaluation of the Union legislation on blood, tissues and cells identified a legal gap in terms of Regulation for some therapies made from substances of human origin (SoHO) that cannot necessarily be defined as blood, tissues, cells or organs. It concerns in particular therapies like human Faecal Microbiota Transplants (FMT) and Breast Milk (BM), whose use entails the need to avoid transmission of diseases from donors, a key concern for all SoHO therapies. The revision of the Union legislative frameworks (blood and tissues and cells) aims to cover this gap and it plans to address safety and quality requirements for these therapies.

Dedicated guidelines on safety and quality will therefore have to be implemented by a new group of actors with expertise on these therapies, and supervised by the SoHO authorities. It is estimated that around 200 new entities or establishments, working with BM or FMT, will be regulated under the new SoHO legislation. This action will help actors and establishments for the preparation of the implementation of these new legal requirements.

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

Objectives

This action aims to bring together sector professionals, for BM (topic (a)) and for FMT (topic (b)), and to facilitate the implementation of new SoHO Regulation (guidelines and legislative requirements as well as the compliance with oversight tasks), in order to allow the safe, effective and qualitative preparation and use of these SoHO-based therapies.

Strand (scope)

This action is part of the "Health Systems and Healthcare Workforce" strand, and it will contribute to "strengthening the implementation of the legislation on blood, tissues and cells and organs". More specifically, this action will support harmonisation across national competent authorities in the field of organs.

Activities that can be funded (scope)

The activities for both topics (a) and (b) are:

1) building an expert forum on breast milk and an expert forum on faecal microbiota transplants;

2) developing, for each SoHO-based therapy, a common set of draft guidelines, with this expert forum, and based on existing initiatives (e.g. professional societies' work, work in research actions);

3) possible future updating of the guidelines, taking account of the new EU legislative framework;

4) providing an implementation plan for establishments/entities in order to implement SoHO requirements, which will also consider the compliance with technical guidelines as well as with oversight provisions (entity and establishment authorisations, preparation process authorisations, inspections, vigilance and traceability); and

5) training and dissemination programme.

These activities are to be developed taking account the commonalities and specificities of both SoHO-based therapies, i.e. BM and FMT (respectively in topic a and b)

Specific mandatory deliverables and/or milestones

The mandatory deliverables are the same for both topics a and b

- Set-up of an expert forum including mandate, rules of procedure and proposed membership.

- Set of draft guidelines for entities/ establishments to implement technical standards, agreed amongst professionals and authorities where possible, and indicating points with divergent views

- Set of draft guidelines for entities/ establishments to comply with oversight requirements, agreed amongst professionals and authorities where possible, and indicating points with divergent views

- A proposed approach for future updating of guidelines

- Gap analyses, recommended actions and implementation plan for entities to implement guidelines on technical standards and on oversight.

- Agreed training programme including necessary tools (manuals, surveys)

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

The two topics should provide up-to-date guidelines on:

a) technical safety and quality aspects for BM (topic (a)) and for FMT (topic (b));

b) implementation of the legal requirements by establishments preparing these substances covered by both subtopics and applying therapies based on them.

They will also create a forum where key experts including Member States authorities can be engaged also in the future whenever the guidelines need to be updated, or when further advice is needed on their implementation.

Both subtopics will support the implementation of the new Union legislative framework on SoHO for entities preparing BM or FMT.

The result of the topic on faecal microbiota will consider the coherence with pharmaceutical actors/legislation, so that actors from both sectors (SoHO and Pharmaceuticals) can look into technical rules for faecal microbiota collected under SOHO and later to be used for manufacturing of pharmaceuticals.

The result of the subtopic on breast milk will consider the coherence with food actors/legislation, so that actors from both sectors (SoHO and food) can look into technical rules for breast milk collected under SOHO and later to be used for the manufacturing of food products.

Specific action-level indicators for reporting purposes for both topics

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

- Numbers of entities/establishments involved

- Number of BM/FMT prepared by these entities/establishments

- Numbers of guidelines developed and agreed with professionals and SoHO authorities

Special requirements

Type of applicants targeted	Topic a: Civil society organisations (professional associations, foundations, NGOs and similar entities) with expertise in the field of neonatology Topic b: Civil society organisations (professional associations, foundations, NGOs and similar entities) with expertise in the field of gastroenterology.
Specific eligibility criteria applicable to the consortium composition	Applications may be either by a single applicant or a consortium (no minimum requirement)

EU4H-2023-PJ-10 — Call for Proposals: action grants on Facilitating Organ

Paired Exchange (HS-g-23-51)

Background and policy context

In Europe, patients are on waiting lists for long periods before receiving an organ transplant due to difficulties to find a compatible donor.

Kidney transplants can involve a living donor, usually a willing donor that is family related to the patient. When this donor does not match in terms of immunology to the patient, exchanges can be organised to match an incompatible donor-recipient pair with another one, and eventually create a series of matches. Such exchange schemes are being developed among some Member States to increase the probability of finding matches (in those countries where the enrolment of such pairs is allowed by national legislation). The development of a software including the matching algorithm (of donor-recipient pairs) is ongoing via a European Cooperation in Science and Technology (COST) action (funded by Horizon 2020 / IG15210 -Software for Transnational Kidney Exchange Programmes) and it is expected to be ready by the end of 2022.

In view of the scarcity of organs available for transplantation, there is a need to strengthen the exchange schemes among Member States, with a clear added value for European patients, as such exchange schemes can save the life of patients.

Objectives

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

This action will apply the common algorithm for matching donor-patient pairs, among the participants and will develop its application.

Strand (scope)

This action is part of the "Health Systems and Healthcare Workforce" strand, and it will contribute to "strengthening the implementation of the legislation on blood, tissues and cells and organs". More specifically, this action will support harmonisation across national competent authorities in the field of organs.

Activities that can be funded (scope)

This action will apply the common algorithm for matching donor-patient pairs, among the participants and will develop its application by:

a) developing the modalities for participating to the cross-border exchange schemes, including agreement and uptake by the different national allocation offices;

b) feeding the algorithm with harmonised pair data via a common IT platform between participants;

c) developing common support protocols among participants, covering all related aspects like oversight, governance, funding, follow-up of donors and patients, in order to allow that transplantations are taking place.

Specific mandatory deliverables and/or milestones

Mandatory deliverables/milestones apart from those listed already in the call text (project website, project leaflet, common support protocols):

- Improved IT platform for matching donor-patient pairs and protocols for feeding and using it, based on testing/experiences by several Member States' allocation offices;

- Operational and financial plan, including governance plan for the sustainable use of the IT platform;

- Guidelines for effective implementation, at national level, and participating to a cross-border exchange scheme for kidney transplants (when enrolment of donor-recipient pairs is allowed by national legislation);

- Website and leaflet to disseminate and exchange good practices.

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

The results are the following:

a) a joint cross-EU allocation system to facilitate Organ Paired Exchange on kidney transplants;

b) development, agreement and use of common protocols, platforms and guidelines to increase the opportunities for patients looking for a kidney transplant;

c) More transplants and better treatment options for patients and increase their quality of life.

The action will contribute to the recovery after the COVID-19 crisis which led to a significant amount of missed donations and transplant opportunities.

Specific action-level indicators for reporting purposes

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

- Number of Member States participating,

- Number of professionals organisations,

-Number of entities/centres participating,

- Number of donor-recipient pairs enrolled into the IT platform,

- Number of match runs performed,

Number of matches identified,

- Number of kidney transplants realised

- Number of patients affected

Special requirements

Type of applicants targeted	Member States' authorities/ allocation offices and professional organisations such as European Organ Exchange organisations and European professional societies.
Specific eligibility criteria applicable to the consortium	Applications may be either by a single applicant or a consortium (no minimum requirement)

composition	

EU4H-2023-PJ-11 — Call for proposals for a program on orphan medical devices, in particular targeting paediatric patients (HS-g-23-65)

Background and policy context

Medical devices and In Vitro Diagnostic Medical Devices (IVDs) have a fundamental role in saving lives by providing innovative healthcare solutions for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease.

Medical devices are subject to Regulation (EU) 2017/745, while IVDs are subject to Regulation (EU) 2017/746.

For the purpose of this action orphan devices[32] are medical devices, including in vitro diagnostic medical devices, that benefit a relatively small group of patients in the treatment or diagnosis of a disease or condition.

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

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

This action supports the policy priority to support the implementation of the medical devices and in vitro diagnostic medical devices legislations and it implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, and supporting innovation regarding such products (Article 3, point (c) of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (c) and (h) of Regulation (EU) 2021/522.

Objectives

This action aims to support non-profit organisations or consortia that provide a platform for academic bodies, scientific societies, developer of devices, in particular SMEs, and NGOs with a specific interest in innovative paediatric devices to help foster and guide the development of orphan devices, for paediatric patients, in particular in areas of unmet medical needs. It takes inspiration from the Paediatric Device Consortia Grants Program of the US Food and Drugs Administration (FDA).

Strand (scope)

This action is part of the Health Systems and Healthcare Workforce related to the implementation of Regulations on medical devices and in vitro diagnostic medical devices.

[32] Exact definition of orphan devices is under discussion by the Medical Device Coordination Group (MDCG) - orphan device task-force.

Activities that can be funded (scope)

The activities may include, among other things, intellectual property advising; prototyping; engineering; laboratory and animal testing; grant-writing; and clinical investigation design. The eligible entities should facilitate the development, production, and distribution of orphan devices, in particular for paediatric patients by:

a) encouraging innovation and connecting relevant players (e.g. academia, scientific societies, users) with orphan device ideas with potential manufacturers;

b) mentoring and managing orphan device projects through the development process, including product identification, prototype design, device development, and marketing;

c) connecting developers of innovative devices and physicians to existing financing resources;

d) assessing the scientific and medical merit of proposed orphan device projects;

e) providing assistance and advice as needed on business development, personnel training, prototype development, and post-marketing needs; and

f) providing regulatory consultation to device developers in support of achieving CE marking for the orphan device.

A successful entity, which could also be a consortium formed by the eligible entities, can support orphan medical device advancement through all stages of development: concept formation, prototyping, preclinical, clinical, manufacturing, marketing, and commercialization.

To accomplish this work, a successful entity should unite natural persons, associations, or institutions to provide the following capabilities: knowledge of the clinical needs for orphan devices, business planning, regulatory advising, intellectual property protections and other legal expertise, as well as scientific, engineering, pre-clinical, and clinical capabilities.

A successful entity which could also be a consortium formed by the eligible entities can support orphan medical device advancement through all stages of development: concept formation, prototyping, preclinical, clinical, manufacturing, marketing, and commercialization.

To accomplish this work, a successful entity should unite natural persons, association, or institutions to provide the following capabilities: knowledge of the clinical needs for orphan devices, business planning, regulatory advising, intellectual property protections and other legal expertise, as well as scientific, engineering, pre-clinical, and clinical capabilities.

Specific mandatory deliverables and/or milestones

- Report on the advancement of the devices supported for further development and expected future milestones until market access.

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

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

Specific action-level indicators for reporting purposes

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

Special requirements

Type of applicants targeted	scientific societies, academia or research institutions and NGOs, possibly also including SMEs with a particular interest and expertise in the area of the action i.e. development of medical devices, especially for children and/or unmet medical needs
Specific eligibility criteria applicable to the consortium composition	Applications may be either by a single applicant or a consortium (no minimum requirement)
Non-eligible activities	N.A.
Other topic requirements	Priority will be given to projects that support the development of paediatric devices, in particular paediatric cardiac devices. Additional priority will be given to projects that support the development of several orphan devices.

EU4H-2023-PJ-12 — Call for proposal: action grants to contribute to the organisations of conference and events (OA-g-23-89)

Background and policy context

The work programme will support the organisation of conference and events which will meet the objectives of Regulation (EU) 2021/522 during 2023, 2024 or both and contribute to the implementation of legislative and non-legislative initiatives of the Union through actions described in the annual work programmes.

The action will support the promotion and development of the European Health Union policies such as the Europe's Beating Cancer Plan, the Pharmaceutical Strategy for Europe, the Global Health strategy, the upcoming health initiatives such as the Mental Health Communication, and the implementation of Union health legislation.

There is a need to:

(i) timely identify upcoming health challenges and priorities and involve all interested parties such as citizens, patients, health practitioners, scientists, policy makers from

local, regional, national and EU level, in finding possible solutions and alternative ways to address such challenges;

(ii) provide information to individuals for preventing and responding to diseases;

(iii) join efforts with the beneficiaries of the EU funds to inform and communicate about the actions implementing the EU4Health Programme and the results obtained;

(iv) promote the Union health policies complementing the national health policies of the EU Member States.

One of the ways to achieve this is by reaching out to the public and all relevant stakeholders in high level science-policy-society events that provide the optimal fora to facilitate the exchange of ideas and development of feasible solutions.

Objectives

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

The objective of this action is to support the organisation of not-for-profit, EU-wide high-level science-policy-society events that bring together all interested parties such as citizens, patients, practitioners, academics and scientists, policy makers from local, regional, and EU level.

The events will promote and contribute to the development and implementation of the European Health Union touching in a comprehensive way the most salient health issues and EU health priorities.

Up to three proposals of different sizes from will be accepted. Priority will be given to proposals covering several types of health challenges in several Member States and beyond the EU. The challenges addressed beyond EU will relate to the EU global health initiatives and policies.

Proposals should include considerations and state-of-the art activities to facilitate the exchange of ideas and identification of Union-wide and/or global solutions to major health challenges.

These conferences are an opportunity for a discussion on how to work better together at EU level on one or more health-related topics and will involve Member States' authorities and relevant stakeholders to exchange information and good practices on relevant topics in the field of public health.

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

Strand (scope)

The proposal should cover one or more strands of the annual work programme and have clearly defined specific objectives. The thematic areas and sub-areas to be covered may include one or more of the below mentioned topics:

(i) health care systems and workforce including in relation to demographic changes;
(ii) One health approach;

(iii) pharmaceuticals;

(iv) digital transition across health challenges;

(v) major non-communicable diseases such as mental health, cancer, cardiovascular;

(vi) European Health Union: what's next?

Priority will be given to proposals covering several types of the above topics in several Member States, and beyond the EU where necessary.

Activities that can be funded (scope)

The proposals should include at least one of following activities:

a) effective mobilisation of a broad audience with participation of policy makers (EU, national, regional and where necessary global levels), academia, industry, civil society including patients' organisations and other relevant representative);
b) provide a platform for a sounding board to explain Eu health initiatives and health societal challenges;
c) sustainable outreach activities beyond the event with multiplier effect including on social media;
d) facilitate high-level policy dialogues attracting relevant health actors from different relevant sectors;
e) the use of innovative approaches in running the event are a plus.

Priority will be given to proposals covering several of the above activities.

Specific mandatory deliverables and/or milestones

- dedicated pages on the existing website of the organisation; dedicated sessions to Commission policy priorities; etc
- Relevant online, electronic and limited printed materials during and post event
- Comprehensive and impartial event report based on contribution from a broad audience participating on-site and online to the event
- Streaming live services (at least for some parts of the event e.g. plenary sessions), recordings (in line with GDPR)
- Relevant social media activity such as Twitter, LinkedIn, and other relevant social media.

In addition, the event/conferences must have a wide European Union dimension, with as many participants as possible from EU Member States and associated countries to the EU4Health Programme;

- Applicants must clearly describe the dissemination strategy.
- Applicants must clearly describe the methodology, tools, timetable and milestones, deliverables, nature and distribution of tasks;
- Applicants must clearly describe the management structure, competence of staff, responsibilities, decision-making, monitoring and supervision;
- Applicants must ensure that the budget is relevant, appropriate, balanced, and consistent in itself and in relation to the objective/s of the conference.

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

This action will involve public or non-profit making entities, well established, credible and with expertise on organising events in public health domain topics.

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

The action will deliver at least three different high-level events that will promote and contribute to the development and implementation of the European Health Union. The high-level events may be part of the same conference.

The Commission considers that proposals requesting a contribution of EUR 150 000 would allow this specific challenge to be addressed appropriately. This does not prevent applicants to submit proposals requesting a different contribution.

The events should include high level speakers (as mentioned above) and a representative number of stakeholders concerned by the challenges to be discussed. Representatives from the relevant EU institutions will be included as well.

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

Conferences and/or events must have a Union-wide dimension. The events will not focus on a specific condition or disease but will focus on current cross-cutting Union policy issues.

Specific action-level indicators for reporting purposes

Applicants must include data on the following specific action-level indicators in their regular reporting activities, and must be prepared to include additional specific action-level indicators where needed:

- Total number of participants (onsite and online)
- Number of participants by sector, organisation and type of expertise, Member State, and level of responsibility of the participant
- The duration of the social media dissemination post event

Special requirements

Type of applicants targeted	Public or non-profit entities with expertise on organising events in public health domain
Specific eligibility criteria applicable to the consortium composition	Applications may be either by a single applicant or a consortium (no minimum requirement)
Non-eligible activities	Conferences which have already held by the date on which the grant application is submitted are not eligible. Conferences organised by the Presidencies of the European Union fall outside the scope of the present call.
Other topic requirements	Priority will be given to proposals covering several types of health challenges in several Member States and beyond the EU. Priority will be given to proposals covering several types of the topics (under subsection Strand - scope) in several Member States, and beyond the EU where necessary. Priority will be given to proposals covering several

	of the activities (under subsection activities that can be funded - scope). The duration of the action must not exceed 12 months and will be organised in 2023 and/or 2024. The duration of the event is up to 5 calendar days.
Place of implementation	EU Member States, listed EEA countries and countries associated to the EU4Health Programme or countries which are in ongoing negotiations for an association agreement and where the agreement enters into force before grant signature

For more information about EU health policies, see Health and Food Safety.

3. Available budget

The estimated available call budget is **EUR 19.960.000**.

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

Topic	Topic budget
EU4H-2023-PJ-01 — Call for proposals to support access to medical devices for cross border health threats (HERA) (CP-g-23-13)	**EUR 1.750.000**
EU4H-2023-PJ-02 — Call for proposals to support stakeholders on the prevention of NCDs in the area of chronic respiratory diseases (DP-g-23-31-02)	**EUR 1.000.000**
EU4H-2023-PJ-03 — Call for proposals on the prevention of NCDs in the area of mental health including actions supporting vulnerable population groups, such as migrants, refugees, Roma people and displaced people from Ukraine (DP-g-23-32-02)	**EUR 2.360.000**
EU4H-2023-PJ-04 — Call for proposals on prevention of NCDs in the area of dementia and other neurological disorders (DP-g-23-33-02)	**EUR 1.000.000**
EU4H-2023-PJ-05 — Call for proposals to support the implementation of the strategic agenda for medical ionising radiation applications (SAMIRA) – organisation of clinical audit campaigns as a tool to improve quality and safety of medical applications of ionising (CR-g-23-44-01)	**EUR 1.500.000**
EU4H-2023-PJ-06 — Call for proposals: action grants on mental health challenges for cancer patients and survivors Sub-topic (a): Mental health and Cancer (CR-g-23-19.01)	**EUR 8.000.000**
EU4H-2023-PJ-07 — Call for proposals: action grants on mental health challenges for cancer patients and survivors Sub-topic (b): European Code for Mental Health (CR-g-23-19.02)	**EUR 2.000.000**
EU4H-2023-PJ-08 — Call for proposals: action grants on the safety and quality of new Substances of Human Origin (Breast milk, faecal microbiota transplants) (a) HS-g-23-50.01 Breast milk (HS-g-23-50.01)	**EUR 400.000**

EU4H-2023-PJ-09 — Call for proposals: action grants on the safety and quality of new Substances of Human Origin (Breast milk, faecal microbiota transplants) (b) HS-g-23-50.02 Faecal microbiotic transplants (HS-g-23-50.02)	**EUR 400.000**
EU4H-2023-PJ-10 — Call for Proposals: action grants on Facilitating Organ Paired Exchange (HS-g-23-51)	**EUR 600.000**
EU4H-2023-PJ-11 — Call for proposals for a program on orphan medical devices, in particular targeting paediatric patients (HS-g-23-65)	**EUR 500.000**
EU4H-2023-PJ-12 — Call for proposal: action grants to contribute to the organisations of conference and events (OA-g-23-89)	**EUR 450.000**

For the number of grant agreements expected to be signed, per topic, please see the table below.

Topic	Grant agreements expected to be signed
EU4H-2023-PJ-01 — Call for proposals to support access to medical devices for cross border health threats (HERA) (CP-g-23-13)	**1**
EU4H-2023-PJ-02 — Call for proposals to support stakeholders on the prevention of NCDs in the area of chronic respiratory diseases (DP-g-23-31-02)	**3**
EU4H-2023-PJ-03 — Call for proposals on the prevention of NCDs in the area of mental health including actions supporting vulnerable population groups, such as migrants, refugees, Roma people and displaced people from Ukraine (DP-g-23-32-02)	**4**
EU4H-2023-PJ-04 — Call for proposals on prevention of NCDs in the area of dementia and other neurological disorders (DP-g-23-33-02)	**3**
EU4H-2023-PJ-05 — Call for proposals to support the implementation of the agenda for medical ionising radiation applications (SAMIRA) – organisation of clinical audit campaigns as a tool to improve quality and safety of medical applications of ionising (CR-g-23-44-01)	**4**
EU4H-2023-PJ-06 — Call for proposals: action grants on mental health challenges for cancer patients and survivors Sub-topic (a): Mental health and Cancer (CR-g-23-19.01)	**7**
EU4H-2023-PJ-07 — Call for proposals: action grants on mental health challenges for cancer patients and survivors Sub-topic (b): European Code for Mental Health (CR-g-23-19.02)	**1**
EU4H-2023-PJ-08 — Call for proposals: action grants on the safety and quality of new Substances of Human Origin (Breast milk, faecal microbiota transplants) (a) HS-g-23-50.01 Breast milk (HS-g-23-50.01)	**1**
EU4H-2023-PJ-09 — Call for proposals: action grants on the safety and quality of new Substances of Human Origin (Breast milk, faecal microbiota transplants) (b) HS-g-23-50.02 Faecal	**1**

microbiotic transplants (HS-g-23-50.02)	
EU4H-2023-PJ-10 — Call for Proposals: action grants on Facilitating Organ Paired Exchange (HS-g-23-51)	**1**
EU4H-2023-PJ-11 — Call for proposals for a program on orphan medical devices, in particular targeting paediatric patients (HS-g-23-65)	**2**
EU4H-2023-PJ-12 — Call for proposal: action grants to contribute to the organisations of conference and events (OA-g-23-89)	**3**

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

4. Timetable and deadlines

Timetable and deadlines (indicative)	
Call opening:	15 June 2023
Deadline for submission:	17 October 2023 – 17:00:00 CET (Brussels)
Evaluation:	November-December 2023
Information on evaluation results:	January 2024
GA signature:	July 2024

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 Search Funding & Tenders 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)*

In addition to the previous mentioned mandatory annexes and supporting documents, for topic EU4H-2023-PJ-12 — Call for proposal: action grants to contribute to the organisations of conference and events (OA-g-23-89), applicants need to provide:

- Website address of the previous conferences. If the conference website is not online, a summary report of each of the conferences should be provided;
- Draft programme of the conference to be held;
- Statutes of the applicant(s);
- Declaration of absence of conflict of interest from industry (free format).

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 it is submitted.

Eligible participants (eligible countries)

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

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

- eligible non-EU countries:
  - listed EEA countries and countries associated to the EU4Health Programme or countries which are in ongoing negotiations for an association agreement and where the agreement enters into force before grant signature (list of participating countries)

Beneficiaries and affiliated entities must register in the Participant Register — 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 eligibility criteria, for each of the topics, are mentioned in section 2 above.

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 persons[33].

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'[34]. ⚠ 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 *(see list above)* may participate in the call and can sign grants if the negotiations are concluded before grant signature (with retroactive effect, if provided in the agreement).

EU restrictive measures — Special rules apply for certain entities *(e.g. entities subject to EU restrictive measures under Article 29 of the Treaty on the European Union (TEU) and Article 215 of the Treaty on the Functioning of the EU (TFEU)[35] and entities*

[33] See Article 197(2)(c) EU Financial Regulation 2018/1046.
[34] For the definitions, see Articles 187(2) and 197(2)(c) EU Financial Regulation 2018/1046.
[35] 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.

covered by Commission Guidelines No 2013/C 205/05[36]). 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 Rules for Legal Entity Validation, LEAR Appointment and Financial Capacity Assessment*.

Consortium composition

See special conditions for each topic under section 2 above.

Eligible activities

Eligible activities are the ones set out in section 2 above, per each topic.

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
EU4H-2023-PJ-01 — Call for proposals to support access to medical devices for cross border health threats (HERA) (CP-g-23-13)	**24-36**
EU4H-2023-PJ-02 — Call for proposals to support stakeholders on the prevention of NCDs in the area of chronic respiratory diseases (DP-g-23-31-02)	**36**

[36] Commission guidelines No 2013/C 205/05 on the eligibility of Israeli entities and their activities in the territories occupied by Israel since June 1967 for grants, prizes and financial instruments funded by the EU from 2014 onwards (OJEU C 205 of 19.07.2013, pp. 9-11).

EU4H-2023-PJ-03 — Call for proposals on the prevention of NCDs in the area of mental health including actions supporting vulnerable population groups, such as migrants, refugees, Roma people and displaced people from Ukraine (DP-g-23-32-02)	**36**
EU4H-2023-PJ-04 — Call for proposals on prevention of NCDs in the area of dementia and other neurological disorders (DP-g-23-33-02)	**36**
EU4H-2023-PJ-05 — Call for proposals implementation of the agenda for medical ionising radiation applications (Samira action plan) – organisation of clinical audit campaigns as a tool to improve quality and safety of medical applications of ionising (CR-g-23-44-01)	**36**
EU4H-2023-PJ-06 — Call for proposals: action grants on mental health challenges for cancer patients and survivors Sub-topic (a): Mental health and Cancer (CR-g-23-19.01)	**36**
EU4H-2023-PJ-07 — Call for proposals: action grants on mental health challenges for cancer patients and survivors Sub-topic (b): European Code for Mental Health (CR-g-23-19.02)	**36**
EU4H-2023-PJ-08 — Call for proposals: action grants on the safety and quality of new Substances of Human Origin (Breast milk, faecal microbiota transplants) (a) HS-g-23-50.01 Breast milk (HS-g-23-50.01)	**18**
EU4H-2023-PJ-09 — Call for proposals: action grants on the safety and quality of new Substances of Human Origin (Breast milk, faecal microbiota transplants) (b) HS-g-23-50.02 Faecal microbiotic transplants (HS-g-23-50.02)	**18**
EU4H-2023-PJ-10 — Call for Proposals: action grants on Facilitating Organ Paired Exchange (HS-g-23-51)	**12-36**
EU4H-2023-PJ-11 — Call for proposals for a program on orphan medical devices, in particular targeting paediatric patients (HS-g-23-65)	**12-36**
EU4H-2023-PJ-12 — Call for proposal: action grants to contribute to the organisations of conference and events (OA-g-23-89)	**12**

The recommended duration is indicated above for each topic. Extensions are possible, if duly justified and through an amendment.

Project budget

Topic	Project Budget (€)
EU4H-2023-PJ-01 — Call for proposals to support access to medical devices for cross border health threats (HERA) (CP-g-23-13)	**1.750.000**
EU4H-2023-PJ-02 — Call for proposals to support stakeholders on the prevention of NCDs in the area of chronic respiratory diseases (DP-g-23-31-02)	**333.333**
EU4H-2023-PJ-03 — Call for proposals on the prevention of NCDs in the area of mental health including actions supporting vulnerable population groups, such as migrants, refugees, Roma people and displaced people from Ukraine (DP-g-23-32-02)	**590.000**

EU4H-2023-PJ-04 — Call for proposals on prevention of NCDs in the area of dementia and other neurological disorders (DP-g-23-33-02)	**333.333**
EU4H-2023-PJ-05 — Call for proposals implementation of the agenda for medical ionising radiation applications (Samira action plan) – organisation of clinical audit campaigns as a tool to improve quality and safety of medical applications of ionising (CR-g-23-44-01)	**375.000**
EU4H-2023-PJ-06 — Call for proposals: action grants on mental health challenges for cancer patients and survivors Sub-topic (a): Mental health and Cancer (CR-g-23-19.01)	**1.142.857**
EU4H-2023-PJ-07 — Call for proposals: action grants on mental health challenges for cancer patients and survivors Sub-topic (b): European Code for Mental Health (CR-g-23-19.02)	**2.000.000**
EU4H-2023-PJ-08 — Call for proposals: action grants on the safety and quality of new Substances of Human Origin (Breast milk, faecal microbiota transplants) (a) HS-g-23-50.01 Breast milk (HS-g-23-50.01)	**400.000**
EU4H-2023-PJ-09 — Call for proposals: action grants on the safety and quality of new Substances of Human Origin (Breast milk, faecal microbiota transplants) (b) HS-g-23-50.02 Faecal microbiotic transplants (HS-g-23-50.02)	**400.000**
EU4H-2023-PJ-10 — Call for Proposals: action grants on Facilitating Organ Paired Exchange (HS-g-23-51)	**600.000**
EU4H-2023-PJ-11 — Call for proposals for a program on orphan medical devices, in particular targeting paediatric patients (HS-g-23-65)	**250.000**
EU4H-2023-PJ-12 — Call for proposal: action grants to contribute to the organisations of conference and events (OA-g-23-89)	**150.000**

This does not however preclude the submission/selection of proposals requesting other amounts. The grant awarded may be lower than the amount requested.

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 Participant Register 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, a beneficiary, requesting an EU-contribution of ≥ EUR 750 000 EUR, shall submit 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 annual accounts (profit and loss account and the balance sheet) for

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
- request that you are replaced or, if needed, reject the entire proposal.

For more information, *see Rules for Legal Entity Validation, LEAR Appointment and Financial Capacity Assessment*.

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).

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 participate[37]:

- 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 misconduct[38] (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant)
- committed fraud, corruption, links to a criminal organisation, money laundering, terrorism-related crimes (including terrorism financing), child labour or human trafficking (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant)
- shown significant deficiencies in complying with main obligations under an EU procurement contract, grant agreement, prize, expert contract, or similar (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant)
- guilty of irregularities within the meaning of Article 1(2) of EU Regulation 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 that[39]:

- 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

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

[38] 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.

[39] See Article 141 EU Financial Regulation 2018/1046.

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 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 Funding & Tenders Portal Terms and Conditions)*. 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 problem-solving 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 milestones and deliverables 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 inhabitant 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
  - C.1 Travel and subsistence
  - C.2 Equipment
  - C.3 Other goods, works and services
- D. Other cost categories: n/a
- E. Indirect costs

Specific cost eligibility conditions for this call:

- personnel costs:
  - SME owner/natural person unit cost[40]: Yes
- travel and subsistence unit cost[41]: 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
  - kick-off meeting: costs for kick-off meeting organised by the granting authority are eligible (travel costs for maximum 2 persons, return ticket to Brussels and accommodation for one night) only if the meeting takes place after the project starting date set out in the Grant Agreement; the starting date can be changed through an amendment, if needed

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

[41] Commission Decision 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).

- 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
- other ineligible costs: No

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 **30%** 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.

⚠ 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 guarantees

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 formally NOT linked to individual consortium members, which means that you are free to organise how to provide the guarantee amount *(by one or several beneficiaries, for the overall amount or several guarantees for partial amounts, by the beneficiary concerned or by another beneficiary, etc)*. It is however important that the requested amount is covered and that the guarantee(s) are sent to us 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.

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).

For more information, *see* AGA — Annotated Grant Agreement.

11. How to submit an application

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

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

a) **create a user account and register your organisation**

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

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

b) **submit the proposal**

Access the Electronic Submission System via the Topic page in the Search Funding & Tenders 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 IT Helpdesk.

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

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).

- **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 double funding —** There is a strict prohibition of double 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 to two different EU actions.

- **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).

- **Combination with EU operating grants —** Combination with EU operating grants is possible, if the project remains outside the operating grant work programme and you make sure that cost items are clearly separated in your accounting and NOT declared twice *(see AGA — Annotated Grant Agreement, art 6.2.E).*

- **Multiple proposals —** Applicants may submit more than one proposal for *different* projects under the same call (and be awarded a 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 one of them (or it 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 EU Financial Regulation, information about EU grants awarded is published each year on the Europa website.

  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 Funding & Tenders Portal Privacy Statement.