



EU4Health Programme (EU4H)

Call for proposals under the Annual Work Programme 2022

EU4H-2022-PJ

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EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HADEA)

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CALL FOR PROPOSALS

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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 2021/522](#) (EU4Health Regulation)¹
- [Regulation 2018/1046](#) (EU Financial Regulation)²

The call is launched in accordance with the 2022 EU4Health Work Programme³ and will be managed by the European **Health and Digital Executive Agency, (HaDEA)** ('Agency').

The call covers the following **topics**:

EU4H-2022-PJ-01: Call for proposals to monitor and strengthen the implementation of innovative approaches to prostate, lung and gastric cancer screening at Union level (**CR-g-22-09.01/02/03**)

EU4H-2022-PJ-02: Call for proposals on prevention of NCDs – (other than cardiovascular diseases and diabetes) (**DP-g-22-06.05**)

EU4H-2022-PJ-03: Call for proposals on promoting mental health (**DP-g-22-07.01/03**)

Each project proposal 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.

EU4H-2022-PJ-04: Call for proposals to support the implementation of the Regulation on health technology assessment – training of patient and clinical experts contributing to joint health technology assessment activities (**HS-g-22-20.01/02**)

EU4H-2022-PJ-05: Call for proposals to support increased capacity of notified bodies for medical devices (**HS-g-22-19.03**)

EU4H-2022-PJ-06: Call for proposals to provide training for health workforce, including digital skills (**HS-g-22-15.01**)

EU4H-2022-PJ-07: Call for proposals to support Member States and other relevant actors to implement relevant results of innovative public health research in relation to vaccination against COVID-19 (**CP-g-22-03.01**)

EU4H-2022-PJ-08 Call for proposals to develop early warning features and guidance in the area of pricing through the EURIPID database, based on competition cases (**HS-g-22-17.01**)

We invite you to read the **call documentation** carefully, in particular this Call Document, as well as the EU4Health Model Grant Agreement, the [EU Funding & Tenders Online Manual](#) and the [EU Grants](#)

¹ [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).

² [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

³ [Commission Implementing Decision C\(2022\) 327 final of 14/01/2022](#) concerning the adoption of the work programme for 2022 and the financing decision for the implementation of the EU4Health programme.

[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, expected results, expected impact, mandatory specific milestones and deliverables, and the indicators (sections 1 and 2);
 - timetable, project duration 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 website⁴ 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

⁴ [Public Health Europe - European Commission - EU | Public Health \(europa.eu\)](#)

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.

Grants shall involve co-financing. Grants paid by the Union shall not exceed 60 % of eligible costs for an action relating to an objective of the Programme. In cases of exceptional utility, the contribution by the Union may be up to 80 % of eligible costs.

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

2.1 Topic EU4H-2022-PJ-01

EU4H-2022-PJ-01: CR-g-22-09.01/02/03 Call for proposals to monitor and strengthen the implementation of innovative approaches to prostate, lung and gastric cancer screening at Union level

A – Background and policy context

Cancer prevention and early detection offer the best chance of beating cancer and saving lives. Currently, the 2003 Council Recommendation on Cancer Screening in the Union⁵ endorses population-based cancer screening for the early detection of breast, cervical and colorectal cancer. As of 2020, 25 Member States had introduced population-based screening in their National Cancer Control Plans programmes for breast cancer, 22 countries for cervical cancer and 20 for colorectal cancer. As announced in the Europe's Beating Cancer Plan, the Commission will make a proposal by 2022 to update that Council Recommendation and ensure the latest available scientific evidence is reflected, including the possible extension of screening to other cancers, for instance prostate, lung, and gastric cancers.

Prostate cancer is the most commonly diagnosed cancer in men with an incidence rate⁶ of 158.7 per 100 000 in Member States and a 5-year relative overall survival rate of 83.4% in Europe. Although it is well-known that Prostate Specific Antigen (PSA) tests in population-based screening programmes would contribute to early detection thereby reducing the prostate cancer mortality rate, the discussion on over-diagnosis and over-treatment has pushed for a revision of the screening approaches at Union level.

Lung cancer is the second most diagnosed cancer among males and the third among females in Member States for the year 2020; the estimated incidence⁷ for the year 2020 is 97.2 per 100 000 in males and 43.9 in females among Member States. Corresponding values for mortality are 15.7

⁵ Council Recommendation 2003/878/EC of 2 December 2003 on cancer screening ([OJ L 327, 16.12.2003, p. 34](#)).

⁶ Age-adjusted incidence rates in 2020. European Cancer Information System.

⁷ Age-adjusted incidence rates in 2020. European Cancer Information System.

and 7.2, respectively. The National Lung Screening Trial⁸ showed that individuals randomly assigned to screening with low-dose computed tomography (CT) scans had 20% lower lung cancer mortality than those screened with conventional chest radiography. However, some investigators suggested that the ratio between benefit and harm could be improved through various means, in particular by reducing the impact of over-diagnosis. Furthermore, the exposure of large groups of healthy individuals to ionising radiation as part of population-based lung cancer screening calls for the development of common low-dose CT protocols, quality assurance and patient dose assessment, in line with European legal requirements for radiation protection⁹.

Gastric cancer is one of the most common cancers in the Union, with an incidence¹⁰ of 22.4 per 100 000 in males and 10.6 in females, and a 5-year relative survival rate of 23.7% in males and 27.7% in females, with a wide variation among Member States. Early gastric cancer detection could improve the survival rate, although different elements may contribute. *Helicobacter pylori* (*H. pylori*) infection is recognised as an important cause of gastric cancer, and its eradication could reduce the incidence and mortality of gastric cancer, although the debate is still open.

The estimation of the direct costs of these three types of cancers shows that they are among the highest when compared to other cancers, with lung and prostate being the two most costly cancers.

This action stems from the Europe’s Beating Cancer Plan and implements the EU4Health Programme’s general objective of improving and fostering health in the Union (Article 3, point (a)), through the specific objectives defined in Article 4, point (a), of Regulation (EU) 2021/522.

B – Objectives pursued

The aim of this action is to provide Member States with evidence-based knowledge to be transferred to further design, plan, and implement prostate, lung, and gastric cancer screenings. Methodological approaches will be aligned and coordinated with the European Guidelines and Quality Assurance Schemes for breast cancers.

C – Description of the activities to be funded under this topic

This action will support the optimisation of knowledge transfer, a better understanding of the needs, and the design, planning and development of possible options for future implementation of targeted screening on prostate, lung, and gastric cancers. In addition, the action will support initiatives to fill the existing gaps in knowledge and to fine-tune and improve the Member States’ approaches to the early detection of prostate, lung, and gastric cancer. It will help to align and ensure consistency in addressing a set of basic requirements that are currently being dealt with in a piece-meal manner in Member States.

These activities will develop and roll-out pilot projects through pan-European cooperation, with a special focus on addressing questions that are still open, including on cost-benefit and optimal benefit-harm balance and potential impact on health inequality of prostate, lung and gastric cancer screening programmes including the identification of appropriate financing mechanisms.

D – Expected results and impacts

Evidence-based data, including from risk-benefit and cost-effectiveness studies and trials, will provide Member States with essential information for the design, planning and roll-out of potential

⁸ N Engl J Med. 2011 Aug 4;365(5):395-409.

⁹ Council 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 Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (BSS Directive).

¹⁰ Age-adjusted incidence rates in 2020. European Cancer Information System.

lung, prostate, and gastric cancer screening, including the best strategies and target groups to take into consideration in function of the available resources.

The initiatives implemented by this action will include a multistep approach to support Member States to organise the evaluation of the practical implementation and the continuous improvement of such screening programmes. The support will include: (1) needs assessment of Member States, taking into account the different epidemiology and populations at risk for lung, prostate and gastric cancers; (2) periodical information on benefit-harm balance and cost-effectiveness of the screenings; (3) regular review of new available approaches; (4) the design, planning and implementation of at least two pilot projects per type of cancer, with the objective of assessing the concrete feasibility of the screenings, fulfilling the requirements of national or regional health authorities; and (5) at least three highly visible conferences targeting all three types of cancers.

E – Specific mandatory deliverables and/or milestones

(in addition to those listed in section C and D above)

According to the multistep approach indicated under point D, mandatory deliverables include (per sub-topic):

(1) One Report, to be delivered no later than 6-8 months from the signature of the contract, on the state of play about prostate, lung and gastric cancer screening/early detection development since 2016 in Member States, and EEA countries, inclusive of information on ‘opportunistic’ screening initiatives organised in public and private setting. The Report will include also information on if and how the three types of cancer screenings are addressed in the National/Regional Cancer Control Plans or, in absence of a Cancer Control Plan, in comparable documents addressing the three types of cancer.

(2) One Report, developed in parallel to the first one and with the same deadline, assessing the Member States’ needs related to prostate, lung and gastric cancer screening and early detection.

(3) A set of guidelines and technical papers and protocols to help to design, plan, pilot, roll out and monitor and evaluate prostate, lung, and gastric cancer screenings programmes in the future. The set will include the costing estimation of each steps and will be delivered no later than one year after the signature of the contract.

(4) At least one pilot project per subtopic. Pilot projects will address one or more specific challenges per subtopic, in particular to address main issues still under debate and/or for which the results of the piloting are considered of major relevance to throw light on those specific topics. Pilot projects can be planned and rolled out since the signature of the contract and their outcomes will be delivered, in form of project reports and/or peer review publications (one report for each pilot project implemented) at the end of the action, that is expected to have a duration of two years.

All the activities under section E will take into account the content of the Scientific Opinion on Cancer Screening of the Group of Chief Scientific Advisors, which will be delivered end of February 2022, and that will inform the Commission to help the preparation of the proposal for an update of the Council Recommendation on cancer screening in the EU. The beneficiaries will also take into account the work done and ongoing of the European Commission Initiative on Breast and Colorectal Cancer, and the recommendations of the European Guide on Quality Improvement in Comprehensive Cancer Control, with specific reference to governance, organisation, and evaluation of cancer screening.

F – Specific action-level indicators for reporting purposes

Applicants shall collect data on the following specific action-level indicators in their regular reporting activities in case of award:

<ul style="list-style-type: none"> - Number of Member States providing input to the first report – per subtopic - Number of Member States providing input to the second report – per subtopic - Number of guidelines, technical papers, protocols delivered – per subtopic - Detailed road-map indicators of the three pilot projects - Number of Member states enrolled in the pilot projects - Number of pilot projects completed per sub-topic <p>The applicants are required to include in their proposals additional specific action-level indicators which will be agreed with the Commission during the grant agreement preparation.</p> <p>The Commission may require the awardees to collect data for additional specific action-level indicators, where needed to complement the above indicators.</p>	
G – Budget	
Available budget for this topic:	Subtopic-1: CR-g-22-09.01 (prostate cancer) EUR 10 000 000 Subtopic-2: CR-g-22-09.02 (lung cancer) EUR 10 000 000 Subtopic-3: CR-g-22-09.03 (gastric cancer) EUR 10 000 000
Proposals to be awarded under this topic:	Up to 3 proposals, each proposal addressing 1 different subtopic: 1 addressing prostate, 1 lung, and 1 gastric cancer.
H – Expected duration of project	
The duration of proposals should range between 12 and 36 months (see section 6 of the call document). Given the complexity of the activities to be funded under this topic, the recommended length of a project is 24 months.	

Special requirements

Applicants – specific eligibility criteria	Academia and education establishments, research institutes, national and regional health authorities dealing with cancer screening programmes, hospitals, civil society organisations (associations, foundations, NGOs and similar entities), expert networks and established networks in the field of public health. For this specific topic, proposals by a single applicant are also eligible.
Specific eligibility criteria applicable to the consortium composition	1 proposal per subtopic. One applicant may cover more than one subtopic (i.e. one proposal per sub-topic).
Non-eligible activities	NO

Financial support to third parties	NO
Place of implementation	NO
Ethics/Security measures	NO

2.2 Topic EU4H-2022-PJ-02

EU4H-2022-PJ-02: DP-g-22-06.05 Call for proposals on prevention of NCDs - other NCDs (different from cardiovascular diseases and diabetes)

A – Background and policy context

NCDs are responsible for 87% of the disease burden in the Member States and improved health promotion and disease prevention can reduce the prevalence of NCDs by as much as 70%. The costs of treating NCDs are high and expected to grow further, also considering the Union's aging population. COVID-19 has shown that NCDs can dramatically increase the negative impact of other diseases; the childhood obesity rate was included in the Commission's strategic resilience dashboard; the economic case for prevention has been made by the OECD.

The Commission supports the Member States in their efforts to reduce the burden of non-communicable diseases, and thus to reach the health targets of the United Nation's 2030 Agenda for Sustainable Development. In this context, the Commission is working on a new initiative, 'Healthier Together – EU NCD Initiative'¹¹, which includes five action strands: cardiovascular diseases, diabetes, chronic respiratory diseases, mental health and neurological disorders, and a horizontal strand on health determinants. In each of these strands, the reduction of health inequalities will be tackled.

Besides the actions to be taken forward in the context of this new initiative, stakeholders, including health professionals' associations and civil society and patients' organisations, have an important role in tackling NCDs, and in particular those NCDs other than cancer and that do not fall under the five strands mentioned above.

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

B – Objectives pursued

The aim of the action is to reduce the burden of NCDs targeting NCDs other than those in the five action strands of the 'Healthier Together – EU NCD Initiative' and cancer; for example, kidney diseases and liver diseases, auto-immune diseases, musculo-skeletal conditions etc., by increasing awareness, sharing knowledge and building capacity to improve public health, especially at local level.

C – Description of the activities to be funded under this topic

Activities to be funded will include the transfer of promising practices and approaches, which contribute to tackling the burden of NCDs other than cancer and those in the five action strands of the 'Healthier Together' initiative.

¹¹ https://ec.europa.eu/health/non-communicable-diseases/overview_en

The civil society organisations (NGOs, professional and patient groups) will implement targeted projects and activities, complementing the Member States’ efforts in the design, planning and implementation of best practices, including support to the definition of public health guidelines and healthcare guidelines, to the preparation and roll out of new policy approaches, to the pilot testing of innovative practices, and support actions such as training and twinning, health communication or health literacy. Activities should also include an equity dimension and aim at reducing health inequalities.

Proposals should include evidence of effectiveness of practices and approaches, and preference will be given to those already tested on the ground with positive outcome. These practices and approaches can be targeted at one or more specific groups, such as different age groups, health care workers and different patient groups. Practice transfer is to be implemented through pilot projects, and in consultation with representatives from the community or target group concerned. Funded activities will also need to include a brief process evaluation of the implementation at the pilot sites, as well as a plan for further roll-out of practice implementation in the participating countries.

In parallel, NGOs and professional and patient groups will have the opportunity to engage in the implementation of complementary actions. Such engagement may include the provision of input for the preparation of public health guidelines, awareness actions, training, piloting or other actions that can benefit citizens directly.

D – Expected results and impact

The action will contribute to the implementation of projects on disease prevention and health promotion, which is expected to reduce the burden of NCDs other than the five action strands of the initiative ‘Healthier Together – EU NCD Initiative’ and cancer, for example, auto-immune diseases, musculo-skeletal conditions, etc.. The action is expected to result in increased awareness, knowledge sharing and capacity building, especially at local level, in Member States.

The expected results will include initiatives to complement the Member States’ efforts in the design, planning and implementation of best practices, such as support for the development of public health guidelines, 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 twinning, health communication or health literacy; and implementation of best practices in health promotion and disease prevention. The short-term impact will be an increased number of public health interventions being scaled up in all Member States and improvements in disease prevention and health promotion, and management policies related to NCDs.

It is expected that the piloting of the practices will contribute to efforts to reduce the burden from non-communicable diseases and have a positive impact at national and local levels in the participating Member States. In particular, it is expected the action will support stakeholders, especially those working at grassroots level, strengthening community-based knowledge sharing, awareness and capacity building.

The short-term impact would be achieved through 1. the piloting of an increased number of public health interventions, and 2. increasing awareness and building capacity. The long-term impact would be the identification of promising approaches with a potential for EU wide transfer. Networking between national and local actors will also help in building capacities for stakeholder involvement in developing public health actions.

E – Specific mandatory deliverables and/or milestones

(in addition to those listed in sections C and D above)

The project(s) should pilot the transfer of promising practices and/or approaches, report on the results, deliver a brief process evaluation, and propose a plan for wider use in tackling NCDs other

<p>than cancer and those targeted in the ‘Healthier Together – EU NCD Initiative’; for example, kidney diseases and liver diseases, auto-immune diseases, musculo-skeletal conditions etc.</p>	
<p>F – Specific action-level indicators for reporting purposes</p>	
<p>Applicants shall collect data on the following specific action-level indicators in their regular reporting activities in case of award:</p> <p>Promising practices and/or approaches:</p> <ul style="list-style-type: none"> - Number of Member States implementing best practices developed under the funded action. - Number of stakeholder organisations involved by type of organisation i.e. private sector, public sector, joint private-public organisation or company, not-for-profit sector, NGO private organization, NGO, and others. - Number of individuals involved by age group i.e. 15-24; 25-49; 50-64; 65-79; 80 and more. - Number of people reached (by target group). <p>Awareness</p> <ul style="list-style-type: none"> - Dissemination material produced by type (e.g. n. of brochures, leaflets, web page). - Number of stakeholders outreached by awareness activities. - Number of pilot projects concluded. - Number of Member States integrating best practices developed under the funded action in their health and social systems. <p>The applicants are required to include in their proposals additional specific action-level indicators which will be agreed with the Commission during the grant agreement preparation.</p> <p>The Commission may require the awardees to collect data for additional specific action-level indicators, where needed to complement the above indicators.</p>	
<p>G – Budget</p>	
Available budget for this topic:	EUR 5 million
Proposals to be awarded under this topic:	Up to 7 proposals
<p>H – Expected duration of project</p>	
<p>The duration of proposals should range between 12 and 36 months (see section 6 of the call document). Given the complexity of the activities to be funded under this topic, the recommended length of a project is 24 months.</p>	

Special requirements for this call topic

Applicants – specific eligibility criteria	Civil society organisations supporting the priority areas (health professional associations, patients’ organisations, foundations, NGOs and similar entities)
Specific eligibility criteria applicable to the consortium composition	The consortium must include at least one NGO active in the field of health at Union level.
Non-eligible activities	NO
Financial support to third parties	NO

Place of implementation	NO
Ethics/Security measures	NO

2.3 Topic EU4H-2022-PJ-03

EU4H-2022-PJ-03: DP-g-22-07.01/03 Call for proposals on promoting mental health

A – Background and policy context

Mental health is an integral and essential component of health. It is critical to individual well-being, as well as to social and economic participation. Prior to the COVID-19 pandemic, the total costs arising from mental health problems accounted for more than 4% of GDP across the Member States (Health at a Glance: Europe 2018). The heavy individual, economic and social burdens of mental illness are not inevitable.

Although many Member States have policies and programmes to address mental illness at different ages, the distribution of these actions is uneven throughout the life course. Furthermore, the COVID-19 pandemic has immediate and long-term consequences, including on mental health, which require action that focuses on vulnerable groups, including children, and refugees and migrant populations. Hence, there is an acute need to increase awareness, knowledge sharing and capacity building in the area of mental health.

The Commission supports Member States to reduce the burden of non-communicable diseases in order to reach the UN SDGs. The Commission is working on a new Initiative, 'Healthier Together', which includes five strands: cardiovascular diseases, diabetes, chronic respiratory diseases, mental health and neurological disorders, and a horizontal strand on health determinants. In each of these strands, the reduction of health inequalities will be tackled.

In addition, the Commission has established the Steering Group on Promotion and Prevention (SGPP) to support Member States in reaching the health targets of the UN SDGs. The expert group provides advice and expertise to the Commission to foster exchanges of relevant experience, policies and practices between Member States on how to tackle the burden of NCDs in the Union. Therefore, addressing mental health challenges through the identification and transfer of best practices, which are developed and implemented successfully in one country, can have a concrete, direct, positive impact for citizens, health systems and society.

This action will provide support to stakeholders in implementing best practices promoting children and adolescent mental health and well-being, with a focus on vulnerable groups, such as children living in deprived areas. It will contribute to giving young people more and better opportunities for the future, in line with the activities of the 2022 European Year of Youth as declared by the Commission¹².

This action supports the policy objective of reducing the burden of NCDs and meets the following EU4Health Programme general objective of improving and fostering health in the Union (Article 3, point (a)) through the specific objectives in Article 4, points (a) and (i), of Regulation (EU) 2021/522.

B – Objectives pursued

The aim of the action is to increase awareness, knowledge generation and sharing, and capacity building in the area of mental health. Activities will include the transfer of best practices, as it was indicated by the SGPP, on children's and adolescents' mental health and well-being.

C – Description of the activities to be funded under this topic

¹² https://ec.europa.eu/commission/presscorner/detail/en/ip_21_5226

<p>Specifically, the actions will support interested stakeholder organisations, to come together to discuss and exchange mental health practices and knowledge, to implement validated best practices and evidence-based projects. The activities should focus on the needs of specific and/or vulnerable groups, in particular children and adolescents.</p> <p>The actions developed by civil society and health professionals' organisations to improve mental health, namely by exchanging and implementing best practices, and implementing activities that will increase awareness, knowledge sharing and support for health professionals' training, including the development of necessary guidance and/or training material, such as video tutorials, manuals, etc.</p> <ul style="list-style-type: none"> - subtopic 1: implementing the best practice (Icehearts¹³) to improve life skills and social, psychological and emotional resources among socially vulnerable children and adolescents (DP-g-22-07.01). - subtopic 2: implementing the best practice (Let's Talk about Children¹⁴) to support mental health and wellbeing of young people and their families in vulnerable groups (DP-g-22-07.3).
<p>D – Expected results and impact</p>
<p>The action will implement the best practices 'Icehearts' and 'Let's Talk about Children' to address the mental health and well-being of children and adolescents (e.g. in schools, and through sport programmes).</p> <p>The short-term impact would be achieved through an increased number of interventions being scaled up in Member States providing long-term professional support for vulnerable young people to prevent social exclusion, promote psychosocial well-being and enhance social skills. The long-term impact would be to identify solutions to tackle specific mental health issues, both at personal and societal level. Networking between experts and additional cross-learning other than via practice transfer per se, will also provide benefits for developing and improving public health and social inclusion policies.</p>
<p>E – Specific mandatory deliverables and/or milestones <i>(in addition to those listed in sections C and D above)</i></p>
<p>Actions funded under this topic shall transfer the above-mentioned best practices to other Member States and embed them in their health and social systems.</p> <p>Practice transfer is to be implemented through pilot projects, and in consultation with representatives from the community or target group concerned. Funded activities will also need to include a brief process evaluation of the implementation at the pilot sites, as well as a plan for further roll-out of practice implementation in the participating countries.</p> <p>The proposals are expected to build on the outcomes of the previous EU-funded work on mental health as well as on lessons learned on the transnational transfer of good practices, in particular those acquired via other projects funded via the Health Programme that focus on good practice transfer.</p>
<p>F – Specific action-level indicators for reporting purposes</p>
<p>Applicants shall collect data on the following specific action-level indicators in their regular reporting activities in case of award:</p>

¹³ https://ec.europa.eu/health/other-pages/basic-page/online-marketplace-event-best-practices-risk-factors-non-communicable-diseases_en

¹⁴ https://ec.europa.eu/health/other-pages/basic-page/online-marketplace-event-best-practices-risk-factors-non-communicable-diseases_en

<p>Best practices:</p> <ul style="list-style-type: none"> - Number of stakeholder organisations involved by type of organisation i.e. private sector, public sector, joint private-public organisation or company, not-for-profit sector, NGOs, private organisation or other. - Number of stakeholder organisations reached via awareness activities by type of organisation i.e. private sector, public sector, joint private-public organisation or company, not-for-profit sector, NGOs, private organisation or other. - Number of individuals involved by age group i.e. 9 or younger, 10-15; 15-24; 25-49; 50-64; 65 and above. - Number of individuals involved by socio-economic status i.e. employer, employee, self-employed, retired, unemployed. - Number of dissemination materials and activities produced by type i.e. brochures, leaflets, web page, social media communications, events and others. <p>The applicants are required to include in their proposals additional specific action-level indicators which will be agreed with the Commission during the grant agreement preparation.</p> <p>The Commission may require the awardees to collect data for additional specific action-level indicators, where needed to complement the above indicators.</p>	
G – Budget	
<p>Available budget for this topic:</p> <p>Proposals to be awarded under this topic:</p>	<p>Dp-g-22-07.01-sub-topic 1 EUR 4 000 000</p> <p>DP-g-22-07.03 sub-topic 2 EUR 4 000 000</p> <p>One single proposal for each sub-topic will be funded. One proposal can address only one sub-topic</p>
H – Expected duration of project	
<p>The duration of proposals should range between 12 and 36 months (see section 6 of the call document). Given the complexity of the activities to be funded under this topic, the recommended length of a project is between 24 and 36 months.</p>	

Special requirements for this call topic

Applicants – specific eligibility criteria	Academia and educational institutions, civil society organisations supporting the priority areas (health and social professional associations, schools, foundations, NGOs and similar entities).
Specific eligibility criteria applicable to the consortium composition	Applications by a consortium of minimum 5 eligible entities from 5 different eligible countries are accepted. The consortium must include at least one NGO active in the field of mental health at Union level, and at least one NGO working in the area of youth and/or representing young people.
Non-eligible activities	NO
Financial support to third parties	NO

Place of implementation	NO
Ethics/Security measures	NO

2.4 Topic EU4H-2022-PJ-04

EU4H-2022-PJ-04: HS-g-22-20.01/02 Call for proposals to support the implementation of the Regulation on health technology assessment – training of patient and clinical experts contributing to joint health technology assessment activities

A – Background and policy context

As laid down in the Regulation on health technology assessment ('the HTA Regulation')¹⁵, patient and clinical experts will play an important role in implementing the new framework. In order to ensure that joint work is of the highest scientific quality and reflects the state of the art, the HTA Regulation establishes that external experts with relevant in-depth specialised expertise should provide input on joint clinical assessments and joint scientific consultations. Such experts should include clinical experts in the therapeutic area concerned, patients affected by the disease, and other relevant experts on, for example, the type of technology concerned or issues related to the relevant clinical study design. In addition, patient organisations and learned societies will have the opportunity to provide input through the Stakeholder Network.

The EUnetHTA joint actions took the first steps to engage external experts in their activities, however currently there is still further need to engage patients and clinical experts as experts contributing to joint scientific consultations and joint clinical assessments. There is therefore a need to put in place appropriate training programmes for both patient and clinical experts. Such training should be based on the work carried out by EUnetHTA joint actions and the subsequent adaptation to fulfil the needs set out in the HTA Regulation. This action should ensure the appropriate and timely contribution to the joint activities that should start at the implementation date. Transparency on funding as well as representativeness and independence of the experts and organisations involved are key in the appropriate implementation of the action.

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

B – Objectives pursued

The action will support a timely implementation of the new legislation through capacity building activities. It is divided in two subtopics: subtopic a) on patient experts, subtopic b) on clinical experts.

C – Description of the activities to be funded under this topic

a) Increasing the capacity of patient organisations and learned societies to provide robust and meaningful input to HTA activities carried out by the Coordination Group and its sub-groups, including dissemination of the output produced;

b) Increasing the knowledge of patients and clinical experts on the new Union HTA legal framework, clarifying their role when invited to contribute to joint HTA activities for their subject matter

¹⁵ Regulation EU (2021)/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (OJ L458, 22.12.2021, p.1-32).

expertise and acting in individual capacity (rather than representing any particular organisation, institution, or Member State);

c) Ensuring the appropriate implementation of the rules to ensure the independence and impartiality of patients and clinical experts involved in joint HTA work.

D – Expected results and impact

The action under each sub-topic is expected to:

a) develop training programmes for patients and clinical experts participating in their individual capacity to joint scientific consultations and joint clinical assessments;

b) contribute to the appropriate implementation of the rules to ensure the independence and impartiality of patients and clinical experts involved in joint HTA work;

c) raise awareness among patient and clinical experts on the new Union legal framework on HTA and stimulate their engagement with HTA bodies at national and Union level, including dissemination of produced output.

E – Specific mandatory deliverables and/or milestones

(in addition to those listed in sections C and D above)

For subtopic a) on patient experts

- Training programme targeted to patients experts. Training programmes should be developed in English and made available, also online, in as many EU official languages as possible.
- Training sessions. Training sessions could be carried out face to face or online or in combination. If only face to face, the minimum number of training sessions should be 6, if only online, the minimum number of these training sessions should be 10.
- List of national and EU-wide patient organisations per disease area (as a minimum on cancer, including rare cancers) who could support the joint work of Coordination Group in the framework set out by the HTA Regulation.
- List of candidate patient experts trained by the national and/or EU-wide patient organisations who could provide input to joint clinical assessments and joint scientific consultations as set out by the Regulation on HTA (as a minimum in the area of cancer, including rare cancers).
- Dissemination tools (e.g. website, newsletter, leaflet) to increase awareness about the Regulation on HTA among patient organisations.

For subtopic b) on clinical experts

- Training programme targeted to clinical experts. Training programmes should be developed in English and made available, also online, in as many EU official languages as possible.
- Training sessions. Training sessions could be carried out face to face or online or in combination. If only face to face, the minimum number of training sessions should be 6 , if only online, the minimum number of these training sessions should be 10.
- List of national and EU-wide organisations such as healthcare professionals, clinical and learned societies per disease area (as a minimum for cancer, including rare cancers) who could support the joint work of Coordination Group as set out in the HTA Regulation.
- List of candidate clinical experts who could provide high-level scientific input to joint HTA work, as set out by the Regulation on HTA, following the training programme (as a minimum in the area of cancer, including rare cancers).
- Dissemination tools (e.g. website, newsletter, leaflet) to increase awareness about the Regulation on HTA among organisations such as healthcare professionals, clinical and learned societies respectively.

F – Specific action-level indicators for reporting purposes					
<p>Applicants shall collect data on the following specific action-level indicators in their regular reporting activities in case of award:</p> <p>For subtopic a)</p> <ul style="list-style-type: none"> - Number of training sessions developed for patients experts - Number of participants per training session and programme - Number of national and EU-wide patient organisations participating to the training programmes developed by this action - Number of national and EU-wide patient organisations identified per disease area (as a minimum for cancer, including rare cancers) - Number of candidate patient experts identified and trained per disease area (as a minimum for cancer, including rare cancers) - Number of dissemination documents (e.g. newsletter, leaflet) produced to increase the awareness of patients about the Regulation on HTA. <p>For subtopic b)</p> <ul style="list-style-type: none"> - Number of training sessions developed for clinical experts - Number of participants per training session and programme - Number of national and EU-wide healthcare professionals’ organisations and learned societies participating to the training programmes developed by this action - Number of national and EU-wide healthcare professionals’ organisations and learned societies identified per disease area (as a minimum for cancer, including rare cancers) - Number of candidate clinical experts per disease area (as a minimum for cancer, including rare cancers) - Number of dissemination documents (e.g. newsletter, leaflet) produced to increase the awareness of clinical experts about the Regulation on HTA. <p>The applicants are required to include in their proposals additional specific action-level indicators which will be agreed with the Commission during the grant agreement preparation.</p> <p>The Commission may require the awardees to collect data for additional specific action-level indicators, where needed to complement the above indicators.</p>					
G – Budget					
<p>Available budget for this topic:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Subtopic a) HS-g-22-20.01</td> <td style="width: 50%;">Subtopic a) EUR 500 000</td> </tr> <tr> <td>Subtopic b) HS-g-22-20.02</td> <td>Subtopic b) EUR 500 000</td> </tr> </table> <p>Proposals to be awarded under this topic: One proposal per sub-topic</p>		Subtopic a) HS-g-22-20.01	Subtopic a) EUR 500 000	Subtopic b) HS-g-22-20.02	Subtopic b) EUR 500 000
Subtopic a) HS-g-22-20.01	Subtopic a) EUR 500 000				
Subtopic b) HS-g-22-20.02	Subtopic b) EUR 500 000				
H – Expected duration of project					
<p>The duration of proposals should range between 24 and 36 months (see section 6 of the call document). Given the complexity of the activities to be funded under this topic, the recommended length of a project is 24 months</p>					

**Special requirements
(for both subtopics)**

Applicants – specific eligibility criteria	Civil society organisations (associations, foundations, NGOs and similar entities), professional medical societies; competent health authorities; academia and education establishments, research organisations For this specific topic, applications by a single applicant are also eligible.
Specific eligibility criteria applicable to the consortium composition	The consortium must include at least one applicant who can provide documented evidence on: <ul style="list-style-type: none"> - Experience in developing training programmes. - Experience/capacity to ensure swift dissemination of information to the patient community and medical community at large. The Consortium should ensure a balanced geographical coverage of the Union.
Non-eligible activities	NO
Financial support to third parties	NO
Place of implementation	NO
Ethics/Security measures	NO

2.5 Topic EU4H-2022-PJ-05

EU4H-2022-PJ-05: HS-g-22-19.03 Call for proposals to support increased capacity of notified bodies for medical devices

A – Background and policy context

The MDR and IVDR greatly rely on the capacity of notified bodies to certify such products, ensuring the placing on the market of devices compliant with the high level of safety and performance standard set out in the legislation. If notified bodies' capacity falls short, the key objective of the legislation to secure access and availability of safe and performant devices to the health sector and ultimately to patients in the Union is jeopardised. There is therefore a need to increase capacity of notified bodies to secure a proper and smooth application of the legislation especially in IVDs, which is largely composed by SMEs and where the new Regulation identifies many new essential tasks to be performed by notified bodies with specialised expertise.

The limited capacity of notified bodies currently represents a bottleneck for those market operators that are ready to implement the Regulations but unable to find notified bodies available to certify their devices. On the other hand, several market operators have shown poor preparedness and incur delays to adapt to the high-level standards set up by the Regulations which has increased the expected time spent by notified bodies to certify such medical devices. In summary, the current situation raises serious concerns about potential risk of shortages and disruption of supply of devices, especially critical IVDs.

<p>This action supports the policy priority to respond to support the implementation of the legislation and implements the EU4Health Programme’s general objective of strengthening health systems (Article 3, point (d)) through the specific objectives defined in Article 4, points (h) and (i), of Regulation (EU) 2021/522.</p>
<p>B – Objectives pursued</p>
<p>This action will contribute to addressing serious concerns about the lack of availability of vital devices in the medium to long term by increasing capacity of notified bodies and preparedness of market operators, in particular SMEs, with a particular focus on IVDs.</p>
<p>C – Description of the activities to be funded under this topic</p>
<p>a) Supporting training, coaching and internship activities addressed to medical devices’ notified bodies as well as third-party entities (conformity assessment bodies) on the process to become a notified body for medical devices;</p> <p>b) Capacity building activities such as webinars, workshops, targeted feedback and informative sessions addressed to market operators;</p> <p>c) Appraisal of the certification demand, with the objective to identify the types of devices for which availability of notified bodies is particularly low or lacking;</p> <p>d) Proposing solutions to facilitate matching the demand of market operators with the availability of notified bodies, in particular in the area of IVDs where SMEs are prominent.</p>
<p>D – Expected results and impact</p>
<p>The action is expected to increase the capacity of notified bodies, increase preparedness of market operators in particular in the area of IVDs (including SMEs) and facilitating the match of demand from the market with the availability of capacity in notified bodies. This ultimately will contribute to secure availability of safe and performant devices in the best interest public health and patients’ safety in Union, thus safeguarding essential objectives of the new regulatory framework.</p>
<p>E – Specific mandatory deliverables and/or milestones <i>(in addition to those listed in sections C and D above)</i></p>
<p>For the purpose of this action, medical devices shall be understood as medical devices and <i>in vitro</i> diagnostics medical devices, as defined in Article 2(1) of Regulation (EU) 2017/745 and Article 2(2) of Regulation (EU) 2017/746, respectively, unless otherwise specified.</p> <p>The applicants should provide the following deliverables:</p> <ul style="list-style-type: none"> - For the activities related to point (a) and (b) of section C as above: at least two training sessions/year; in addition, for point (b) min number of participants 50. - For point (a), market analysis to create a list of existing and potential new notified bodies (public or private) interested to receiving the training, coaching and internships; this list has to be kept up-to date for the all duration of the action. - For point a) the internship activity has to be conducted at the manufacturer premises in order to increase the capacity building of existing and potential new notified bodies. - For point (c), a manufacture’s survey should be carried out as soon as the action starts, ensuring a broad coverage of manufacturers placing medical devices on the EU market. In particular, the survey has to ensure inclusion of both EU and non-EU manufacturers, big companies as well as SMEs and should cover all the different types of medical devices (see devices codes listed in Regulation 2017/2185). An update of the survey (or more if needed) should be launched throughout the duration of this action. - For (d), a proposed mechanism for notified bodies to provide updated information (to be kept as confidential) on their availability to certify medical devices in particular for <i>in vitro</i>

<p>diagnostics devices. This mechanism needs to be tested within the three months after the action starts.</p>	
<p>F – Specific action-level indicators for reporting purposes</p>	
<p>Applicants shall collect data on the following specific action-level indicators in their regular reporting activities in case of award:</p> <ul style="list-style-type: none"> - List of EU and non-EU manufacturers identified, by size, by action of involvement and branch of activities described in section C (a) to (c) - Number of existing and potential new notified bodies involved by branch of activities described in section C. - Number of training, coaching and internship session developed - Number of people and entities attending to the capacity building activities - Number of new potential notified bodies on medical devices in accordance with MDR and IVDR. - Number of certifications requests received by the notified bodies. <p>The applicants are required to include in their proposals additional specific action-level indicators which will be agreed with the Commission during the grant agreement preparation.</p> <p>The Commission may require the awardees to collect data for additional specific action-level indicators, where needed to complement the above indicators.</p>	
<p>G – Budget</p>	
Available budget for this topic:	EUR 4 000 000
Proposals to be awarded under this topic:	one single proposal
<p>H – Expected duration of project</p>	
<p>The duration of proposals should range between 12 and 36 months (see section 6 of the call document). Given the complexity of the activities to be funded under this topic, the recommended length of a project is 36 months.</p>	

Special requirements

Applicants – specific eligibility criteria	Member States’ competent authorities; academia and education establishments, research institutes, hospitals; international organisations and civil society organisations (associations, foundations, NGOs and similar entities) and private entities (including conformity assessment bodies and notified bodies)
Specific eligibility criteria applicable to the consortium composition	The consortium must include Notified Bodies with documented evidence on assessment of medical devices The consortium should ensure a balanced geographical coverage of the Union.
Non-eligible activities	NO
Financial support to third parties	NO

Place of implementation	NO
Ethics/Security measures	NO

2.6 Topic EU4H-2022-PJ-06

EU4H-2022-PJ-06: HS-g-22-15.01 Call for proposals to provide training for health workforce, including digital skills

A – Background and policy context

The COVID-19 pandemic showed the enormous scope for mutual learning and the importance of sharing knowledge or updating skills to save lives and achieve better health outcomes. The right skills are also essential to mobilise resources in crisis situations. In addition, the access to continuous professional training is one of the most important motivation factors for the health workforce, and equips them with necessary skills to save lives and improve health outcomes.

The European Health Union package puts particular emphasis on improving the resilience of health systems and staff is at the very core of more resilient health systems. On top of a challenge related to staff shortages, the health systems in the Union should also address skills mismatches. This has already been highlighted in the 2017, 2019 and 2021 State of Health in the EU Companion Reports¹⁶, which show that training is key in not only upgrading skills of health workforce, but also in supporting quicker transition to more effective and patient-oriented health models.

This action will address shortages in access to continuous and professional development and training for health professionals (CPD)¹⁷ and it will increase opportunities for training for non-clinical staff working on health planning, procurement and management. This will contribute to the transformation of health systems including digital health solutions.

Improving digital skills is a precondition of a quicker digital transition, one of the priorities for the Commission. Often digital skills are outdated and not adequately considered in professional development, therefore the design of training courses and promoting the results will raise awareness for the need for digital skills, quality of the available training, and the importance of digital skills within the healthcare professions.

Mobilising efforts to address skills mismatches is, among other actions an objective of the EU Pact for Skills¹⁸, which calls for efforts in all the sectors, including health, to support skills necessary to recover quicker from the COVID-19 pandemic and to build more resilient societies and economies. A health partnerships under the EU Pact for Skills will promote digital skills, so this action will directly contribute to it.

The training courses will also pay due attention to the digital dimension and will strengthen the digital literacy and use of digital health tools by the health workforce. Investing in digital skills of health workforce enables the safe and effective use of approved latest digital technologies developments, as the recent OECD analysis highlights¹⁹.

To address existing skills mismatches, the actions can target upskilling and re-skilling to deal with pressing health challenges such as antimicrobial resistance, emerging infectious diseases, multi-

¹⁶ [Companion Report | Public Health \(europa.eu\)](#)

¹⁷ CPD as ‘the educative means of updating, developing and enhancing how doctors apply the knowledge, skills and attitudes required in their working lives’.

¹⁸ Pact for Skills: <https://ec.europa.eu/social/PactforSkills>.

¹⁹ Empowering the health workforce. Strategies to make the most of the digital revolution 2020 <https://www.oecd.org/health/health-systems/Empowering-Health-Workforce-Digital-Revolution.pdf>.

morbidity and chronic diseases and other potential new challenges in the future, depending on the needs of Member States.

This action is closely linked to EU political priorities such as the European Health Union and the EU Pact for Skills. In the implementation, this action will ensure that there is no overlap with projects financed by the NextGenerationEU funds.

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

B – Objectives pursued

The objective of this action is to strengthen the continuous professional development and training through updated or new training courses developed in co-operation with professional associations, education centres and other relevant organisations. This will provide opportunities for up-skilling or re-skilling, taking full advantage of technological developments in line with the EU Pact for Skills (e.g. training will include relevant modules on digital skills).

C – Description of the activities to be funded under this topic

This action will cover the following activities:

- a) developing and implementing training modules of continuous professional development for medical professions including nurses and other health workforce by addressing their needs;
- b) the training courses will include digital skills and other relevant skills needed for surge capacity in crises and for transformation of health systems into new care models providing more integrated health care;
- c) developing and implementing training modules for non-clinical staff working in health systems to contribute to effective, accessible and resilient health systems with a focus on digital skills for procurement, planning and management;
- d) micro credentials in the training courses (in line with the forthcoming Commission’s initiative on micro credentials) could be considered.

This action will complement the activities under the healthcare workforce projects cluster supported under the 3rd Health Programme²⁰ and the joint action (‘A health workforce to meet health challenges - forecasting and planning for workforce in the healthcare sector’) established under the 2021 EU4Health work programme on building capacity in effective forecasting and planning for health workforce.

D – Expected results and impact

The expected results are the following:

- a) newly designed European training modules for health workforce (physically or online) and their implementation; at least 1 module for general medicine, at least 3 modules for specialists professionals, at least 4 modules for nurses, at least 2 modules for non-clinical staff working in health systems or health authorities;
- b) at least seven specific modules to train trainers;

²⁰ Funding & tender opportunities Single Electronic Data Interchange Area (SEDIA)
<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-search>.

- c) improving the digital skills of health workforce as part of patient care;
- d) developing micro-credentials as appropriate in skills for healthcare;
- e) refining the current educational model to adapt the health workforce skills for surge demand in crisis.

This action will impact on the skills underpinning quicker recovery and transition to more resilient health systems. It will also have an impact on:

- a) organisational change, improvement of workload and team work, especially in surge capacity;
- b) the implementation of the Pact for Skills initiative through provision of training opportunities to upskill and reskill especially in digital skills in healthcare.

E – Specific mandatory deliverables and/or milestones

(in addition to those listed in sections C and D above)

Project proposals should include the assessment of needs and the description of the intervention logic, showing how the proposed training courses and modules will contribute to closing the existing and future gaps in skills (both in relation to upskilling and reskilling of health workforce).

Each project proposal should include:

1) the assessment of needs with following elements:

- The analysis of training needs per country and per sector which should distinguish between needs for more basic and/or advanced skills and take into account existing analyses and views of national professional societies and national health authorities;
- The analysis of the most essential needs of target groups to reach by age, gender, specific category of health workforce (clinical and non clinical staff);
- The analysis of the most essential needs according to thematic focus on training demonstrating how selected topics and themes of training will help to address existing and future skills gaps, policy priorities and needs for professional reorientation of staff linked to taking up new functions, changes of functions and ways of working or reorganisation of health systems;
- A mapping of existing continuous training and professional development training possibilities in Member States targeting health professionals (doctors, nurses and other health professionals) and non-clinical staff and explanation how a project proposal addresses existing training gaps.

2) training components with following elements:

- when relevant, training programme/s for ‘Train the trainer’ modules with clear training targets aligned to the needs analysis;
- the most relevant elements needed for developing the training addressing the needs of specific categories of health workforce;
- training programmes developed on the basis of the professional expertise with clear training targets aligned to the needs analysis;
- training should target specialisations recognised in at least 10 Member States²¹;
- training should combine theoretical and practical training modules;
- training should be carried out in at least 5 Member States²² and should be provided in national languages of these countries;
- each training should include components on digital skills;

²¹ Including Countries associated to the EU4Health Programme

²² Including Countries associated to the EU4Health Programme

<ul style="list-style-type: none"> - training plan explaining how training will be organised: selection of participants, selection criteria, duration, forms of training (per hours/per week), selection of trainers, etc; - communication and dissemination plan of these training activities, including by using a userfriendly platform; - overall evaluation plan ; - if relevant, possibility of microcredentials to be provided to each trainee attending the training courses and addressing the specific skills developed during the training (physically or online) or a certificate of training (also provided online); - high quality supporting training materials prepared by the trainer; - training programmes and materials should be available on line for future potential use and dissemination in countries not participating in the projects. <p>3) Mechanisms of co-operation of European professional associations with national associations and national health authorities.</p> <p>4) Monitoring mechanisms ensuring structured and regular reporting on results and impacts of projects.</p> <p>5) Project proposals should, if relevant, demonstrate complementarities with:</p> <ul style="list-style-type: none"> - Reforms and investments included in Resilience and Recovery Plans; - The Flagship initiative Digital Skills for Digital Transformation of Health and Care Systems financed by the Technical Support Instrument (TSI); - Initiatives supported under the Horizon Europe programme, Healthy citizens 2.0: supporting digital empowerment and health literacy of citizens; - Digital education programmes supported under the Digital Europe Programme; - Training initiatives co-funded by the European Cohesion Funds; - Other relevant training initiatives.
<p>F – Specific action-level indicators for reporting purposes</p>
<p>Applicants shall collect data on the following specific action-level indicators in their regular reporting activities in case of award:</p> <ul style="list-style-type: none"> - Number of trainers receiving specific training; - Number of persons who completed the training with a breakdown for each specific target group (General practitioners and specialist doctors, nurses, long-term care personnel, non-clinical staff) and for each country. Number of persons who completed the training by age, gender, specific category of health workforce (clinical and non clinical staff); - Number of persons who completed digital skills courses; - Number of persons who completed training on specific themes (themes defined in training programmes); - Number of participants of training, who obtained continuous Medical Education credits (if applicable according to national frameworks); - Number of certificates of training obtained by participants issued according to developed microcredentials; - Satisfaction rate of participants of the training. <p>The applicants are required to include in their proposals additional specific action-level indicators which will be agreed with the Commission during the grant agreement preparation.</p> <p>The Commission may require the awardees to collect data for additional specific action-level indicators, where needed to complement the above indicators.</p>
<p>G – Budget</p>
<p>Available budget for this topic: EUR 29 000 000</p>

Proposals to be awarded under this topic:	At least 2 million EUR per project proposal Up to 10 project proposals will be selected.
H – Expected duration of project	
The duration of proposals should range between 12 and 36 months (see section 6 of the call document). Given the complexity of the activities to be funded under this topic, the recommended length of a project is 24 months.	

Special requirements

Applicants – specific eligibility criteria	Academia and educational establishments, European association of healthcare professionals, Trade Unions, civil society organisations (associations, foundations, NGOs and similar entities) and Member States' authorities Applicants must provide documented evidence on experience in developing training programmes for clinical and non-clinical staff. For this specific topic, applications by a single applicant are also eligible.
Specific eligibility criteria applicable to the consortium composition	NO
Non-eligible activities	NO
Financial support to third parties	NO
Place of implementation	NO
Ethics/Security measures	NO

2.7 Topic EU4H-2022-PJ-07

EU4H-2022-PJ-06: CP-g-22-03.01: Call for proposals to support Member States and other relevant actors to implement relevant results of innovative public health research in relation to vaccination against COVID-19

A – Background and policy context

The COVID-19 pandemic created a need for fast vaccination of entire populations in Member States, which was a challenge of historic dimensions for many countries, as it required a multitude of steps to be taken successfully. These range from the design of vaccination plans, to the set-up of appropriate infrastructure and easily accessible, sufficiently resourced vaccination services, to communication and outreach activities to ensure high uptake of the vaccines, including activities to address vaccine hesitancy and disinformation on related risks.

The novelty of the vaccines to be administered and the pandemic context made the task even more demanding. Hence, there is a need to gain efficiency and develop strategies in terms of large-scale vaccination for other diseases as well. Large-scale vaccination could contribute to enhanced catch-up

<p>vaccination in the context of routine vaccination programmes rolled out in the Member States that may have been interrupted or delayed during the COVID-19 health crisis.</p> <p>This action supports the policy priority to respond to the COVID-19 crisis and implements the EU4Health Programme’s general objective of protecting people in the Union from serious cross-border threats to health (Article 3, point (b)) through the specific objectives defined in Article 4, points (a) and (b), of Regulation (EU) 2021/522.</p>
<p>B – Objectives pursued</p>
<p>The action aims to support Member States and relevant stakeholders to implement the results of recent and relevant research in relation to vaccination against COVID-19.</p>
<p>C – Description of the activities to be funded under this topic</p>
<p>The action should cover the following activities:</p> <p>a) mapping public health evidence and research results on COVID-19 large-scale vaccination that could be relevant for uptake, including findings, from Member States and outside of the Union;</p> <p>b) identifying challenges and assess the feasibility to implement solutions in Member States, based on the mapping and taking country-specific factors into account;</p> <p>c) developing implementation plans and pilot activities to respond to the current pandemic context or future health crises, or to optimise current routine vaccination practices, including catch-up vaccination;</p> <p>d) implementing the pilot activities in volunteering Member States including the activities identified as potentially most effective (e.g. training programmes for health professionals, awareness-raising campaigns to tackle vaccine hesitancy, health preparedness training programmes, infrastructure initiatives, dedicated events for the exchange of good practices, risk communication and community engagement etc.);</p> <p>e) identifying successful pilot activities and, based on these, develop a robust sustainability plan for continued implementation and toolkits and recommendations for upscaling in other Member States.</p>
<p>D – Expected results and impact</p>
<p>The action is expected to deliver an inventory of relevant innovative public health research on COVID-19 large-scale vaccination and implement plans in relevant Member States taking into account feasibility and country specific factors. This will result, based on pilot projects implemented in several Member States and, after assessment, in the development of sustainability plans and toolkits and recommendations.</p>
<p>E – Specific mandatory deliverables and/or milestones <i>(in addition to those listed in sections C and D above)</i></p>
<p>These activities are expected to increase efficiency in terms of large-scale vaccination, making the best possible use of research results to increase uptake of COVID-19 vaccines and/or other vaccines covered by routine vaccination programmes.</p> <p>A project funded under this topic shall include at least the following deliverables, but must not be limited to those:</p> <ul style="list-style-type: none"> - Mapping public health evidence and research results on COVID-19 large-scale vaccination (point a above) - This should be a deliverable early in the project;

<ul style="list-style-type: none"> - Implementation report from the pilot action (point D above); - Sustainability plan for continued implementation and toolkits and recommendations for upscaling in other Member States (point E above)
F – Specific action-level indicators for reporting purposes
<p>Applicants shall collect data on the following specific action-level indicators in their regular reporting activities in case of award:</p> <ul style="list-style-type: none"> - Number of items (evidence and research results) mapped; - Number of outcomes (analysis, reports, recommendations) produced on the basis of the information identified by the mapping; - Number of Member States implementing solutions and recommendations produced on the basis of the information identified by the mapping;; - Number of implementation plans produced - Number of pilot activities initiated; - Number of Member States participating to pilot activities; - Number of pilot projects considered successful for upscaling; - Number of sustainability plan, toolkits and recommendations for upscaling pilot projects in all MS; - Number of MS and/or Regions, which gave a commitment to the further implementation and uptake. <p>The applicants are required to include in their proposals additional specific action-level indicators which will be agreed with the Commission during the grant agreement preparation.</p> <p>The Commission may require the awardees to collect data for additional specific action-level indicators, where needed to complement the above indicators.</p>
G – Budget
<p>Available budget for this topic: EUR 30 000 000</p> <p>Proposals to be awarded under this topic: Up to 10 project proposals will be selected.</p> <p>Proposals will be awarded according to the ranking of scores received on the award criteria, up to the available budget.</p>
H – Expected duration of project
<p>The duration of proposals should range between 12 and 36 months (see section 6 of the call document). Given the complexity of the activities to be funded under this topic, the recommended length of a project is 36 months.</p>

Special requirements

Applicants – specific eligibility criteria	Academia and education establishments, research institutes, hospitals, expert networks, private entities, Member States’ authorities, and civil society organisations (associations, foundations, NGOs and similar entities)
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	Profound experience in the implementation of large-scale vaccination programmes. Proposals by a single applicant or by a consortium are eligible.
Specific eligibility criteria applicable to the consortium composition	NO
Non-eligible activities	Research/development of vaccines
Financial support to third parties	NO
Place of implementation	NO
Ethics/Security measures	NO

2.8 Topic EU4H-2022-PJ-08

EU4H-2022-PJ-08 HS-g-22-17.01 Call for proposals to develop early warning features and guidance in the area of pricing through the EURIPID database, based on competition cases

A – Background and policy context

The Pharmaceutical Strategy for Europe²³ mentions that the Commission will engage with Member States to foster transparency of price information to help them take better pricing and reimbursement decisions. Prices and pricing decisions influence access to cost-effective and affordable medicines. The 2019 report on the Competition enforcement in the pharmaceutical sector (2009-2017) revealed that the distortion of the price competition in the Union can affect the functioning of internal market²⁴. Voluntary collaborations on pricing, like the EURIPID database²⁵, can support early identification and warning for such practices through exchanges of relevant information at Union level.

This action will contribute to the policy priority to implement the Pharmaceutical Strategy for Europe as it concerns the support of Member States in national pricing and reimbursement policies. 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 of supporting innovation regarding such products (Article 3, point (c)) through the specific objectives defined in Article 4, points (c) and (h), of Regulation (EU) 2021/522.

B – Objectives pursued

The scope of this action is to develop early warning mechanisms and guidance in the area of pricing through the EURIPID database, based on lessons from competition cases, in particular on excessive pricing.

C – Description of the activities to be funded under this topic

This action will create common approaches to verify claims on price information and to provide appropriate guidance to adjust pricing methodologies.

²³ [COM \(2020\) 761 final](#) .

²⁴ <https://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/index.html>

²⁵ European Integrated Price Information Database (EURIPID).

<p>The activities will include the monitoring of strategic sequencing of price increases or threats to de-list reimbursable medicines or withdraw of medicines. These activities may prevent price increases based on unfounded claims to recover investments and increased costs.</p>
<p>D – Expected results and impact</p>
<p>This action will:</p> <ol style="list-style-type: none"> a) strengthen the cooperation between national authorities to address the challenges due to certain commercial practices; b) extend the EURIPID database to develop warning features c) develop relevant and related technical guidance; d) provide an updated guidance document on External Reference Pricing.
<p>E – Specific mandatory deliverables and/or milestones (in addition to those listed in sections C and D above)</p>
<p>The activities will include the monitoring of strategic sequencing of price increases meant to game the External Reference Pricing system and monitoring.</p> <p>The extension of the EURIPID database to develop warning features is meant to identify strategic price increases and threats to de-list or withdraw medicines. As part of the activities, it would be necessary to explore synergies with other databases to complement early warning information (like verification of shortages and/or market withdrawals).</p> <p>The following deliverables should be included:</p> <ul style="list-style-type: none"> - <i>Project Leaflet 1</i>: A leaflet (1-2 pages maximum) to promote the project must be produced at the beginning of the project - <i>Leaflet 2</i>: A leaflet in A4 format (1-2 pages maximum) in a layman language (EN) to promote the output and the results of the project - <i>Layman version of the Executive Summary of the Final Report</i>: This is a short (maximum 10 pages) version of the final report, written for the interested public as a target group. - <i>Public Website</i> Expanded Project’s website with the new features at https://www.euripid.eu - <i>eLeaflets</i> on country background information on national pricing and reimbursement policies - <i>Notification</i> feature on the updates of the list prices, price increases, updates on list of the products covered by their health insurance system etc - <i>Webinars</i> for the users to strengthen cooperation to address certain commercial practices and to implement the guidance on pricing methods and ERP. - <i>User guides</i>: updated user guides information, standardisation manual - <i>Fact sheets</i>: analyses following the format ‘EURIPID quick check’ on specific products with data from the EURIPID database. - <i>Dissemination activities</i>: meetings with EURIPID members and dedicated workshops with key stakeholders - <i>Final report</i>
<p>F – Specific action-level indicators for reporting purposes</p>

Applicants shall collect data on the following specific action-level indicators in their regular reporting activities in case of award:

- Number of leaflets, factsheets, user guide and other communication materials disseminated
- Number of notifications received by type (e.g. list prices, price increases, updates on list of the products covered by their health insurance system, etc)
- Number of webinar and workshops and other dissemination activities organised
- Number of participants to the webinar and workshop
- Satisfaction rate of participants to the webinar and workshop
- Number of additional warning integrated in the database
- Number of countries uptaking ERP guidance document in their national processes
- Number of countries declaring that Euripid has impacted their national pricing and reimbursement system of medicines
- Number of countries providing information (on prices and reimbursement products; on sales data; on MEAs)

The applicants are required to include in their proposals additional specific action-level indicators which will be agreed with the Commission during the grant agreement preparation.

The Commission may require the awardees to collect data for additional specific action-level indicators, where needed to complement the above indicators.

G – Budget

Available budget for this topic: EUR 300 000

Proposals to be awarded under this topic: Up to 300 000 one single proposal

H – Expected duration of project

The duration of proposals should range between 12 and 36 months (see section 6 of the call document). Given the complexity of the activities to be funded under this topic, the recommended length of a project is 36 months.

Special requirements

Applicants – specific eligibility criteria	Member States authorities
Specific eligibility criteria applicable to the consortium composition	A consortium composed of at least 6 eligible applicants established in at least 5 different eligible countries.
Non-eligible activities	NO
Financial support to third parties	NO
Place of implementation	NO
Ethics/Security measures	NO

3. Available budget

The available call budget is **EUR 107 300 000**. This budget might be increased by a maximum of 20%.

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

Topic	Topic budget	Proposals to be awarded	Recommended project duration
<p>EU4H-2022-PJ- 01: CR-g-22-09.01/02/03 Call for proposals to monitor and strengthen the implementation of innovative approaches to prostate, lung and gastric cancer screening at Union level</p>	<p>Sub-topic 1 EUR 10 000 000 Sub-topic 2 EUR 10 000 000 Sub-topic 3 EUR 10 000 000 Total: EUR 30 000 000</p>	<p>Up to 3 proposals, each proposal addressing 1 different subtopic</p>	<p>The duration of proposals should range between 12 and 36 months (see section 6 of the call document). Given the complexity of the activities to be funded under this topic, the recommended length of a project is between 24 and 36 months</p>
<p>EU4H-2022-PJ- 02: DP-g-22-06.05 Call for proposals on prevention of NCDs - other NCDs (different from cardiovascular diseases and diabetes)</p>	<p>EUR 5 000 000</p>	<p>Up to 7 proposals</p>	<p>The duration of proposals should range between 12 and 36 months (see section 6 of the call document). Given the complexity of the activities to be funded under this topic, the recommended length of a project is 24 months.</p>
<p>EU4H-2022-PJ-03: DP-g-22-07.01/03 Call for proposals on promoting mental health</p>	<p>Sub-topic 1 EUR 4 000 000 Sub-topic 2 EUR 4 000 000 Total: EUR 8 000 000</p>	<p>One single proposal for each sub-topic</p>	<p>The duration of proposals should range between 12 and 36 months (see section 6 of the call document). Given the complexity of the activities to be funded under this topic, the recommended length of a project is between 24 and 36 months</p>
<p>EU4H-2022-PJ-04: HS-g-22-20.01/02 Call for proposals to support the implementation of the Regulation on health technology assessment – training of patient and clinical experts contributing to joint health technology</p>	<p>Sub-topic 1 EUR 500 000 Sub-topic 2 EUR 500 000 Total: EUR 1 000 000</p>	<p>One proposal per sub-topic</p>	<p>The duration of proposals should range between 24 and 36 months. Given the complexity of the activities to be funded under this topic, the recommended length of a project is 24 months</p>
<p>EU4H-2022-PJ-05: HS-g-22-19.03 Call for proposals to support increased capacity of notified bodies for medical devices</p>	<p>EUR 4 000 000</p>	<p>One single proposal</p>	<p>The duration of proposals should range between 12 and 36 months (see section 6 of the call document). Given the complexity of the activities to be funded under this topic, the recommended length of a project is 36 months.</p>

<p>EU4H-2022-PJ-06: HS-g-22-15.01 Call for proposals to provide training for health workforce, including digital skills</p>	<p>EUR 29 000 000</p>	<p>At least 2 million EUR per project proposal Up to 10 project proposals will be selected</p>	<p>The duration of proposals should range between 12 and 36 months (see section 6 of the call document). Given the complexity of the activities to be funded under this topic, the recommended length of a project is 24 months</p>
<p>EU4H-2022-PJ-07: CP-g-22-03.01 Call for proposals to support Member States and other relevant actors to implement relevant results of innovative public health research in relation to vaccination against COVID-19</p>	<p>EUR 30 000 000</p>	<p>Up to 10 project proposals will be selected.</p>	<p>The duration of proposals should range between 12 and 36 months (see section 6 of the call document). Given the complexity of the activities to be funded under this topic, the recommended length of a project is 36 months.</p>
<p>EU4H-2022-PJ-08: HS-g-22-17.01 Call for proposals to develop early warning features and guidance in the area of pricing through the EURIPID database, based on competition cases</p>	<p>EUR 300 000</p>	<p>Up to 300 000 EUR one single proposal</p>	<p>The duration of proposals should range between 12 and 36 months (see section 6 of the call document). Given the complexity of the activities to be funded under this topic, the recommended length of a project is 36 months.</p>

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

4. Timetable and deadlines

Timetable and deadline (indicative)	
Call publication:	22 February 2022
Proposal submission opening:	22 February 2022
<u>Deadline for submission of proposals:</u>	<u>24 May 2022 - 17:00:00 CET (Brussels)</u>
Evaluation:	June - July 2022
Information on evaluation results:	September 2022
GA signature:	January 2023

5. Admissibility and documents

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

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 — these 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** (*to be uploaded*):
 - detailed budget table (*template available in the Submission System*)
 - CVs (free format) of core project team
 - activity reports of last year: not applicable
 - list of previous projects, if any (key projects for the last 4 years) (*within template in Part B*)
 - other annexes: not applicable

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 of 70 pages (Part B). Evaluators will not consider any additional pages.

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

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

6. Eligibility

Eligible participants (eligible countries)

In order to be eligible for funding, 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 linked to it (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 the deadline for submission.

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.

Specific cases

Natural persons — Natural persons are NOT eligible for grants (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 persons²⁶.

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'.²⁷

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 — Participants from countries with ongoing negotiations (*see above*) may participate in the call and can sign grants as beneficiaries eligible for funding 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) and entities covered by Commission Guidelines No [2013/C 205/05](#)*). 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).

For more information, see [Rules for Legal Entity Validation, LEAR Appointment and Financial Capacity Assessment](#).

[Consortium composition](#)

Unless stated otherwise in section 2 above (Call topics) 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.

[Activities eligible for funding](#)

Eligible activities are the ones set out in section 2 above for each topic. The following activities are not considered as eligible for funding under this call:

- Those which do not implement the objectives listed in Articles 3 and 4, (as referenced

⁵ For the definitions, see Articles 187(2) and 197(2)(c) EU Financial Regulation [2018/1046](#).

²⁷ See Article 197(2)(c) EU Financial Regulation [2018/1046](#).

in article 12 of the EU4Health Regulation).

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

Projects should normally range between 12 and 36 months (extensions are possible, if duly justified and introduced through an amendment). Indications of the recommended duration are given in section 2 above for each topic under this call (call topics).

Project budget

See section 3.

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.

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*)
- pre-financing paid in instalments
- (one or more) pre-financing guarantees (*see below, section 10*)

or

- propose no pre-financing
- 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, Financial Regulation article 196\(d\)](#).

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 participate²⁸:

- 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 misconduct²⁹ (including if done by persons having powers

²⁸ See Articles 136 and 141 of EU [Financial Regulation 2018/1046](#).

²⁹ 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.

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 crime (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 [Regulation No 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 refused from participation if it turns out that³⁰:

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

8. Evaluation and award procedure

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

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

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

Successively for every group of *ex aequo*³¹ proposals, starting with the highest scored group,

³⁰ See Article 141 EU [Financial Regulation 2018/1046](#).

³¹ Proposals with the same score.

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 and complementarity 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 are 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:

- **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)

- **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)
- - **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.

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 call budget. 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. Retroactive application can be

granted exceptionally for duly justified reasons but never earlier than the proposal submission date.

Project duration: between 12 and 36 months (extensions are possible, if duly justified and through an amendment).

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.

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 awarded may be lower than the amount requested.

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 (maximum **60%**). You can apply for a higher project funding rate (maximum **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 cost³²: Yes
- travel and subsistence unitcost³³: 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

³² 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\(2020\)7715](#)).

³³ 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](#)).

accommodation for one night) only if the meeting takes place after the project starting date set out in the Grant Agreement; the starting date can be changed through an amendment, if needed

- project websites: communication costs for presenting the project on the participants' websites or social media accounts are eligible; costs for *separate* project websites are not eligible

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 **pre-financing** to start working on the project (float of up to **30%** of the maximum grant amount; exceptionally less or no pre-financing). The pre-financing 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.

Pre-financing guarantees

If a pre-financing 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 pre-financing 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.

Pre-financing 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 pre-financing (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):*

- 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 a 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 web-form, 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)
- 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 **up to 12 days before the deadline**: HADEA-HP-CALLS@ec.europa.eu.

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

12.1 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 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 Model 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](#).