

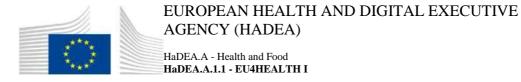
EU4Health Programme (EU4H)

Call for action grants under the Annual Work Programme 2021

EU4H-2021-PJ-02

Version 2.0 25 10 2021

HISTORY OF CHANG		ES	
Version	Publication Date	Change Page	
1.0	13.10.2021	First version.	
2.0	25.10.2021	Changes to Topic EU4H-2021-PJ-06: - Adds clarity about participants profiles, namely existing health data authorisation bodies or access authorities, as well as health data research infrastructures are now included in the eligible applicants profiles; - Clarifies the links with the use cases of EMA/ECDC; - Clarifies the role of the Commission on the definition and selection of use cases and the design of architecture and specifications; - Adds additional possible areas to explore as use case (innovation and personalised medicine); - Highlights the importance of demonstrating the added value of cross-country health data reuse.	8



CALL FOR PROPOSALS

TABLE OF CONTENTS

Int	roduction	5
1.	Background	7
2. imj	Objectives — Themes and priorities — Activities that can be funded — Expected pact	
2.1	Topic EU4H-2021-PJ-06	8
2.2	Topic EU4H-2021-PJ-07	12
2.3	Topic EU4H-2021-PJ-08	15
2.4	Topic EU4H-2021-PJ-09	17
2.5	Topic EU4H-2021-PJ-10	21
2.6	Topic EU4H-2021-PJ-11	23
2.7	Topic EU4H-2021-PJ-12	25
2.8	Topic EU4H-2021-PJ-13	27
2.9	Topic EU4H-2021-PJ-14	31
2.1	0 Topic EU4H-2021-PJ-15	34
2.1	1 Topic EU4H-2021-PJ-16	36
2.1	2 Topic EU4H-2021-PJ-17	39
2.1	3 Topic EU4H-2021-PJ-18	42
3.	Available budget	44
4.	Timetable and deadlines	48
5.	Admissibility and documents	48
6.	Eligibility	49
l	Eligible participants (eligible countries)	49
	Geographic location (target countries)	
1	Duration	51

P	Project budget	51
E	Ethics	51
7.	Financial and operational capacity and exclusion	52
F	Financial capacity	52
(Operational capacity	53
E	Exclusion	53
8.	Evaluation and award procedure	54
9.	Award criteria	55
10.	Legal and financial set-up of the Grant Agreements	56
S	Starting date and project duration	56
N	Milestones and deliverables	57
F	Form of grant, funding rate and maximum grant amount	57
E	Budget categories and cost eligibility rules	58
R	Reporting and payment arrangements	59
P	Pre-financing guarantees	59
C	Certificates	60
L	Liability regime for recoveries	60
P	Provisions concerning the project implementation	60
(Other specificities	61
N	Non-compliance and breach of contract	61
11.	How to submit an application	61
12.	Help	62
12.	1 Important	63
		64
		65

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 2021 EU4Health Work Programme³ and will be managed by the European **Health and Digital Executive Agency**, (HaDEA) ('Agency').

The call covers the following **topics**:

EU4H-2021-PJ-06 Action grants for developing a pilot project for an EU infrastructure ecosystem for the secondary use of health data for research, policy-making and regulatory purposes

EU4H-2021-PJ-07 Action grants to support implementation of best practices on the ground with direct impact on the effort to tackle mental health challenges during COVID-19

EU4H-2021-PJ-08 Action grants to support actions to improve access to human papillomavirus vaccination

EU4H-2021-PJ-09 Action grants for the initiative 'HealthyLifestyle4All': promotion of healthy lifestyles

EU4H-2021-PJ-10 Action grants to reduce liver and gastric cancers caused by infections

EU4H-2021-PJ-11 Action grants for 'EU Cancer Treatment Capacity and Capability Mapping' project - Network of Comprehensive Cancer Centres

EU4H-2021-PJ-12 Action grants to create a 'Cancer Survivor Smart Card'

EU4H-2021-PJ-13 Action grants to support the implementation of best practices in community-based services for the human immunodeficiency virus (HIV) infection and acquired immunodeficiency syndrome (AIDS), tuberculosis, viral hepatitis and sexually transmitted infections.

EU4H-2021-PJ-14 Action grants supporting training activities, implementation, and best practices

EU4H-2021-PJ-15 Action grants for 'Cancer Diagnostic and Treatment for All' including

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(2021) 4793: final of 24/06/2021 on the financing of the Programme for the Union's action in the field of health (EU4Helath Programme) and the adoption of the work programme for 2021.

'Genomic for Public Health'

EU4H-2021-PJ-16 Action grants for the Computer-aided Drug Repurposing for Cancer Therapy Project

EU4H-2021-PJ-17 Action grants to organise and collect data to understand the safety, quality and efficacy of therapies applied in the field of assisted reproduction and based on haematopoietic stem cells

EU4H-2021-PJ-18 Action grants boosting cancer prevention through the use of the European Code against Cancer and other concerted actions

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.

We invite you to read the **call documentation** carefully, in particular this Call Document, as well as the EU4Health Model Grant Agreement, the <u>EU Funding & Tenders Online Manual</u> and the EU Grants AGA — Annotated Grant Agreement.

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

- the <u>Call Document</u> outlines the:
 - background, objectives, scope, activities that can be funded, 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 <u>Online Manual</u> outlines the:
 - procedures to register and submit proposals online via the EU Funding & Tenders Portal ('Portal');
 - recommendations for the preparation of the application;
- the 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 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.

Cancer is the second leading cause of mortality in the Member States after cardiovascular disease. The prevention and control of cancer would benefit the majority of citizens since it shares common risk factors with other non-communicable diseases. Europe's Beating Cancer Plan, which is a key pillar of a stronger European Health Union, tackles the entire cancer disease pathway by means of flagship initiatives, such as launching a Cancer Inequalities Registry, and supporting actions, such as establishing an EU Network of Youth Cancer Survivors. The EU4Health programme will provide the financial support to implement these initiatives that are important to mitigate the impact of the COVID-19 pandemic on cancer control and care.

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,

⁴ <u>Public Health Europe - European Commission - EU | Public Health (europa.eu)</u>

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-2021-PJ-06

Part A - Text to be included in the call document

Topic EU4H-2021-PJ-06: Action grants for developing a pilot project for an EU infrastructure ecosystem for the secondary use of health data for research, innovation, policy-making and regulatory purposes

A – Background and policy context

The EU cross-border provisions and means to access to health data is fragmented which makes particularly difficult the reuse health data collected during healthcare. There is a need to incentivise and fund a pilot project on EU-wide reuse of health data, taking advantage of national authorities' legal basis and capabilities to facilitate access to health data sources through common rules, means and procedures.

The use cases of this pilot should demonstrate the potential of cross-country reuse of health data for research, innovation, policy-making, regulatory activities, and possibly personalised medicine, by connecting the existing health data authorisation bodies or access authorities (i.e. national authorities empowered by national mandate and legal basis to enable access to health data) and other EU-level organisations (e.g., research infrastructures, European health related agencies) and highlight the potential benefits and added value of a large scale infrastructure for the reuse of health data.

An improved coordination of national efforts and harmonisation of the digital infrastructure and data quality would promote the collaboration of several stakeholders involved in the health data processing towards the delivery of better healthcare to citizens. It would contribute to the creation of an ecosystem of infrastructures relying on common standards and policies to enable integration of currently fragmented national data systems while at the same time provide space for diversity and specificity for each research, innovation, policy-making, regulatory needs and possibly personalised medicine.

The action supports the development of the European Health Data Space (EHDS) and the reuse of health data for the research, innovation, policy-making and regulatory activities. It implements the EU4Health Programme's general objective of 'strengthening health systems' (Article 3, point (d)) through the specific objectives defined in Article 4, point (f) of Regulation (EU) 2021/522.

B – Objectives pursued

This consortium will design, develop, deploy and operate a network of nodes (representing different data brokers, holders and data consumers) federated by central services that may be provided by the European Commission.

This pilot will investigate and establish the value of an infrastructure and data ecosystem for the reuse of health data and assess the ability to scale towards a Union-wide infrastructure, as a core component of the European Health Data Space.

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

In particular, it will require to:

a) define and select, jointly with the Commission, key use cases (including necessary health

datasets) that build on health data made available by the consortium partners to demonstrate added value of cross-country reuse of health data;

- b) elicit requirements (business, functional and non-functional) for an IT and data infrastructure (including nodes and central services) to enable Union-wide reuse of health data;
- design, jointly with the Commission, the architecture and the specifications for the building blocks necessary for an IT infrastructure (nodes and central services) to enable Union-wide reuse of health data;
- d) develop, customise or integrate technology, jointly with the Commission, to fulfil the agreed requirements, architecture and specifications, as indicated in points a, b and c;
- e) deploy, at partner level, the nodes, in conformity with the design specifications, and connect them to both the national infrastructure and to the central services;
- f) run the selected use cases over the implemented IT infrastructure (validation of the process);
- g) assess the performance of the selected standards and technological building blocks used and their ability to scale towards a Union-wide infrastructure;
- h) demonstrate how the infrastructure can contribute to support institutions such as EMA and ECDC, to fulfil their needs for real world health data;
- i) provide feedback on legal and governance arrangements for efficient cross-border reuse of health data in the context of the pilot project.

D - Expected results and impacts

The expected results of this action are the following:

- a) Candidate requirements, architecture and specifications for the technological building blocks for an IT and data infrastructure to enable EU-wide reuse of health data;
- b) Deployment of a working IT infrastructure consisting of, at least, 5 nodes (that can be national authorities empowered by national mandate and legal basis to enable access to health data, ERICs and Research Infrastructures); to these nodes, one could add EU agencies and connection with central services enabling Union-wide reuse of health data;
- Report of the assessment performed on the proposed standards and technological building blocks, including findings and lessons learnt on effectiveness and potential to scale towards a Union-wide solution;
- d) Report on candidate legal and governance arrangements for a digital infrastructure for efficient cross border reuse of health data;
- e) Demonstrate the added value of cross-country health data reuse on specific use cases (e.g. scientific research, policy making and regulatory activities).

This pilot aims at reducing risks and unknowns regarding a Union-wide large-scale deployment of an infrastructure for reuse of health data. It would investigate and establish the feasibility and added value of a cross-border infrastructure for the reuse of health data.

The knowledge and know-how acquired during this pilot project will also contribute to a better understanding of the challenges towards the European Health Data Space.

E – Specific mandatory deliverables and/or milestones

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

- a) Analysis report describing the selection of use cases and the business, functional and non-functional requirements, architecture and specifications for the IT infrastructure, including the rationale for the definition of the standards architecture;
 - a. the use of Connecting Europe Facility (CEF) building blocks and the adoption of open standards should be considered in the definition of specifications. The use of CEF building blocks could reduce the costs and development time (it could affect the ability of European Commission to provide central services) as well as facilitate the interoperability between the EHDS and other data spaces being established.
 - b. the use of DCAT Application Profile for data portals in Europe (DCAT-AP) as baseline specification for metadata records should be explored as cornerstone for semantic interoperability in the EHDS and with other European data spaces;
 - c. the selected use cases must aim at covering, among others, the needs of Union bodies that would benefit from the reuse of health data, namely the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC);
- b) the results of the project must be open source and made available through a public repository under a permissive license;
- c) ensure awareness and communication activities for the general public
- d) development, testing, deployment and operation of a re-usable IT infrastructure for the reuse of health data on the basis of the developed specifications and use cases;
 - a. the number of nodes in the IT infrastructure should be enough to demonstrate its scalability and flexibility, as well as to delineate a process for onboarding new nodes;
 - b. at least, 3 national permit/access authorities (national authorities empowered by national mandate and legal basis to enable access to health data), at least 2 ERICs or Research Infrastructures, and possibly EMA/ECDC (or use cases supporting their activity) should be included in the network of the IT infrastructure;
- e) evaluation report of the deployed IT infrastructure and the technological building blocks based on the experience with the execution of the use cases;
 - a. this report should demonstrate how a user journey in the EHDS would look like, identify major challenges and possible solutions towards cross-border/cross-jurisdiction reuse of health data, and be the basis for further development and deployment of the infrastructure for possible Union-wide uptake;
 - b. the user journey (for different purposes: research, innovation, policy-making and regulatory activities, and, if possible, personalised medicine) should explore, at least, the following phases: a) data discovery; b) data availability validation and access negotiation; c) data delivery; e) data processing/analysis; and f) finalisation;
- f) report describing the tested and proposed legal and governance framework and opinion on effectiveness and potential to scale towards a Union-wide solution.

F – Specific action-level indicators for reporting purposes

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

- Number of Data Authorisation Bodies or Access Authorities, Research Infrastructures and ERICs participating in the pilot
- Number of EHDS nodes deployed
- Number of use cases demonstrated

- Number of data sources/datasets made available in the pilot
- Time to process a data access authorisation requests
- Percentage of approved multi-country data authorisation requests
- Percentage of approved multi-country data authorisation requests that have accessed the data.
- Number of administrative steps to approve a multi-country data authorization and comparison with a scenario without the infrastructure
- Estimated costs for a multi-country data access request
- Estimated cost for onboarding a new EHDS node

G - Budget

Available budget for this topic: EUR 5 000 000

Proposals to be awarded under this topic: One single proposal

H – Expected duration of project

The duration of proposals should range between 12 and 24 months (see section 6 of the call document). Given the existence of preliminary know how in this domain, the expected length of the project could be 18 months.

Part B – Special requirements to be included in the call document

Examples of Applicants The applicants' profile and institutional type could be the ones listed in the column to the right. Other types of applicants will be also accepted.	Data Authorisation Bodies or Access Authorities or other Member States' authorities, ERICs or Research Infrastructures
Applicants – consortium composition	A consortium composed by applicant organisations including: a) at least 3 legally established, or in the process of being legally established, national authorities empowered by national mandate and legal basis to enable access to health data and belonging to 3 different EU/EEA countries; and b) at least 2 already established European Research Infrastructure Consortiums (ERICs) or Research Infrastructures Involvement of some the EU agencies in the area of health (e.g. EMA, ECDC) should be sought as part of the project and nodes in the infrastructure, their participation will not be reimbursed as part of the pilot project.
Non-eligible activities	

Financial support to third parties	
Place of implementation	The nodes (gateways enabling cross-border/cross-jurisdiction reuse of health data) shall be mandated and legally empowered to further process health data inside their jurisdiction (EU/EEA or ERIC or Research Infrastructures). The ability to demonstrate how the piloted infrastructure can contribute to support EMA and ECDC to fulfil their needs for real world health data is considered extremely valuable.
Ethics/Security measures	This initiative implies the further processing of personal health data for the purpose of research, policy making and regulatory activities.

2.2 Topic EU4H-2021-PJ-07

Action grants to support implementation of best practices on the ground with direct impact on the effort to tackle mental health challenges during COVID-19

A - Background and policy context

Mental health is an integral and essential component of health. It is critical to individual wellbeing, as well as to social and economic participation. The heavy individual, economic and social burdens of mental illness are not inevitable.

In 2018, approximately 13.5% of hospital beds in the Union were psychiatric care beds with wide disparities between the Member States in the number of beds per 100 000 inhabitants. 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. Fewer countries have programmes targeting the mental health of unemployed people and older people. The total costs of mental health account for more than 4% of GDP across the Member States (Health at a Glance: Europe 2018). Therefore, addressing mental health challenges through the identification and transfer of best practices and implementation of relevant research results is a necessary priority.

Furthermore, the COVID-19 pandemic has immediate and long-term consequences, including on mental health, which require action. The Commission Communication 'Short-term EU health preparedness for COVID-19 outbreaks⁵' calls to support the roll-out of practices that address the mental health impact of COVID-19 and have a potential for improvements and to support health professionals as well as NGOs focusing on mental health challenges during the pandemic. Best practices, which are developed and implemented successfully in one country, can be transferred to other countries with a concrete, direct, positive impact for citizens, health systems and society.

This action supports the policy objective of reducing the burden of NCDs and meets the following the EU4Health Programme's 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

⁵ Short-term EU health preparedness for covid-19 outbreak communication: <u>communication - short-term_eu_health_preparedness.pdf</u> (europa.eu)

(EU) 2021/522.

B – Objectives pursued

The aim of the action is to increase awareness, knowledge sharing and capacity building in the area of mental health

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

Activities will include the transfer of practices shared within the Health Policy Platform network on 'COVID-19 mental health support'. The Commission has set up a dedicated space on 'COVID19 mental health support' within the Health Policy Platform. This allows interested stakeholder organisations to come together to discuss and exchange mental health practices and knowledge. Coordinated by Mental Health Europe, the group includes a focus on the needs of specific and/or vulnerable groups, including children and young people. In addition to exchanging practices, the network on 'COVID-19 mental health support' 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.

D – Expected results and impact

It is expected that the implementation of best practices to address mental health challenges during the COVID-19 pandemic, for example targeting mental health in schools, will have a direct impact on the effort to reduce the burden in the Member States and will support health professionals and improve awareness.

The short-term impact would be achieved through 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, and awareness-building and training capacity for health professionals to strengthen the capacity and capabilities to address the mental health impact of health crisis. The long-term impact would be the identification of solutions to tackle specific mental health issues, both at personal and societal level. Networking between experts will also provide benefits for developing and improving public health policies.

E – Specific mandatory deliverables and/or milestones

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

Activities to be funded will include the transfer of promising practices such as those presented at the high-level conference on the mental health impact of the pandemic (May 2021)⁶ to meet mental health needs that emerged or were exacerbated as a consequence of the pandemic. These practices can be targeted at one or more specific groups, such as vulnerable groups, including health care workers, social workers, migrants, people with pre-existing mental health problems, older people, children and youth in the context of the Covid-19 pandemic. Best practice transfer is to be implemented through pilot projects, and in consultation with representatives from the community or target group concerned. The activities will support stakeholders and service providers, especially those working at grassroots level, to strengthen community-based knowledge sharing, awareness and capacity building with a view to strengthening the response to the mental health impact of the pandemic, especially at local level. 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 rollout of practice implementation in the participating

⁶ Promising practices/approaches such as those available at <u>Health Policy Platform website</u> and conference website will be considered: <u>Mental health and the pandemic: living, caring, acting! | Public Health (europa.eu)</u>

countries. The project(s) should pilot transfer of promising practices and/or approaches, report on the results, deliver a brief process evaluation, and propose a plan for wider implementation in the Member States involved. A reflection on wider lessons learned from the various pilots also as regards opportunities and relevance for further implementation in other EU countries is considered as a plus.

F – Specific action-level indicators for reporting purposes

Applicants must include data on the following indicators in their regular reporting activities in case of award, and must be prepared to include additional specific indicators where needed: Promising practices and/or approaches:

- Number of stakeholder organisations involved (hospitals, long-term care facilities, schools, etc,...)
- Number of vulnerable groups, including health care workers and/or social workers, migrants, people with pre-existing mental health problems, older people, children and youth involved
- Number of targeted groups reached
- Number and types of dissemination material produced (e.g. n. of brochures, leaflets, web page)
- Number of stakeholders outreached by awareness activities

t
į

Available budget for this topic: EUR 750 000

Proposals to be awarded under this topic: Up to 2 proposals

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.

Part B – Special requirements for this call topic

Examples of Applicants The applicants' profile and institutional type could be the ones listed in the column to the right. Other types of applicants will be also accepted.	Public or private non-profit organisations. NGOs active in the field of mental health are recommended to participate in the action
Applicants – consortium composition	The consortium must be composed by at least one NGO active in the field of mental health, preferably at EU level
Non-eligible activities	
Financial support to third parties	n/a
Place of implementation	n/a
Ethics/Security measures	
Applicants – specific eligibility criteria	Public or private non-profit organisations. NGOs active in the field of mental health are

	recommended to participate in the action
Specific eligibility criteria applicable to the consortium composition	- The consortium must be composed by at least one NGO active in the field of mental health, preferably at EU level
Non-eligible activities	
Financial support to third parties	Yes
Place of implementation	No
Ethics/Security measures	

2.3 Topic EU4H-2021-PJ-08

Action grants to support actions to improve access to human papillomavirus vaccination

A – Background and policy context

Cervical cancer is one of the most preventable and treatable forms of cancer. The primary cause of cervical cancer is a persistent infection of the genital tract by a high-risk human papillomavirus (HPV) type. HPV is also associated with other cancers, in both the male and female population.

In May 2018, the World Health Organisation (WHO) called for the elimination of cervical cancer as a public health problem, and set a target of 90% coverage of HPV vaccination in girls by 2030 in the Global Strategy Towards the Elimination of Cervical Cancer as a Public Health Problem drafted in 2019. In the Union, HPV vaccination has been gradually introduced in national immunisation programmes since 2007, but policies and vaccination coverage rates vary across countries.

One of the flagship initiatives of Europe's Beating Cancer Plan is to vaccinate at least 90% of the Union target population of girls and to significantly increase the vaccination of boys by 2030, in order to eliminate cervical cancer and other cancers caused by HPV such as head-and neck and anal cancers. To support this initiative, the Commission will propose a Council recommendation on vaccine-preventable cancers to help address cancer risks associated with HPV infection and other infections.

This action supports the implementation of a Europe's Beating Cancer Plan flagship initiative 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 (j) of Regulation (EU) 2021/522.

B – Objectives pursued

The aim of the action is to contribute to the implementation of Europe's Beating Cancer Plan, which aims to support Member States' efforts to extend the roll-out of routine HPV vaccination of girls and boys to eliminate cervical cancer and other cancers caused by HPV in the coming decade.

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

The action will support civil society organisations, including non-governmental organisations, to complement the Member States' actions according to national and regional needs related to HPV vaccination policies and programmes. The activities which will be funded will include targeted meetings, workshops, and other initiatives to sharing information with national and regional

authorities of Member States, which need to start large-scale HPV vaccination campaigns, with the main objective to receive support through the provision of expertise, best practices, and guidelines covering the planning and roll-out of vaccination campaigns.

These activities may include training (including training of trainers) on how to successfully communicate with parents and patients on HPV vaccination, how to ensure the provision of consistent messages to the public, and the provision of concrete examples on how to support vaccination in other Member States. Activities may include recommendations for the 'bundling' of all adolescent vaccines, including the HPV vaccine, by establishing a policy to check patients' immunisation status at every visit and to always recommend and administer vaccines to those in need. Actions will be designed on the already available evidence-based understanding of behavioural determinants of vaccination acceptance for HPV vaccination.

D – Expected results and impact

The action will contribute to the design, planning and roll-out of an HPV vaccination campaign at Member State level.

The expected impact is the improvement of the vaccination coverage of the target population, and a reduction in the incidence and mortality of cervical and other cancers caused by HPV.

E – Specific mandatory deliverables and/or milestones

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

Not applicable

F – Specific action-level indicators for reporting purposes

Applicants must include data on the following indicators in their regular reporting activities in case of award, and must be prepared to include additional specific indicators where needed:

- Number of training courses organised.
- Number of training of trainers organised.
- Number of people trained.
- Satisfaction rate / feedback of trainees.
- Satisfaction rate / feedback of national/regional authorities responsible for human papillomavirus vaccination programmes.
- Number of trainees having introduced practice at work after the training (to be considered when the number of trainees is limited).
- Number of practices taken up by national and/or regional authorities to complement the national and/or regional human papillomavirus vaccination programmes.
- Number of types of material produced for disseminating expertise, best practices, and guidelines (e.g. studies, reports, handbooks, brochures...).
- Number of countries, organisations and people outreached by actions.

G – Budget

Available budget for this topic: EUR 1 200 000

Proposals to be awarded under this topic: 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 24 months.

Part B – Special requirements for this call topic

Examples of Applicants The applicants' profile and institutional type could be the ones listed in the column to the right. Other types of applicants will be also accepted.	Not applicable.
Applicants – consortium composition	Applications by either a sole applicant or by a consortium are acceptable
Non-eligible activities	N/a
Financial support to third parties	N/a
Place of implementation	N/a
Ethics/Security measures	N/a
Applicants – specific eligibility criteria	No
Specific eligibility criteria applicable to the consortium composition	 Applications by either a sole applicant or by a consortium are acceptable
Non-eligible activities	No
Financial support to third parties	No
Place of implementation	No
Ethics/Security measures	No

2.4 Topic EU4H-2021-PJ-09

Action grants for the initiative 'HealthyLifestyle4All': promotion of healthy lifestyles

A – Background and policy context

Lifestyle factors, including healthy diet and physical activity, have long been recognised as potentially important determinants of cancer risk and other non-communicable diseases (NCDs), such as obesity and cardiovascular disease. The 4th edition of the European Code against Cancer recommends that to reduce their risk of cancer people have a healthy diet, are physically active in everyday life and limit the time spent sitting. However, only 3% of national health budgets are currently spent on health promotion and disease prevention. Therefore, there is a need to support Member States' and stakeholders' actions to promote healthy diets regular physical activity and the creation of physical and social environments where making healthy choices is easy.

The action supports the implementation of the Europe's Beating Cancer Plan objective to improve health promotion through access to healthy diets and physical activity, and implements the

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

B – Objectives pursued

The 'HealthyLifestyle4All' is an initiative, which will build upon the Tartu Call for a Healthy Lifestyle. The aim of this initiative will be to promote healthy lifestyles in the Union, in particular amongst children, and its scope will be widened to involve various Commission services, civil society organisations and the Member States.

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

This specific action will support the 'HealthyLifestyle4All' initiative by strengthening the health literacy component for the promotion of healthy lifestyles with a focus on the school setting, ensuring equal access to the activities by all socio-economic groups, and thereby reducing health inequalities. The work will be done through a holistic approach of a healthy school initiative, supporting Member States to create a healthy school environment. The action will support public authorities to increase opportunities for regular physical activity, to promote healthy lifestyles by exchanges of best practices on health literacy, including the health aspects of the Union school scheme and the promotion of the European Code against Cancer. The project will develop proposals for effective uptake of successful practices on health literacy and healthy lifestyles including, nutrition, regular health-enhancing physical activity and mental health in schools.

This action will support activities involving key actors, including the Member States, regional and local governments, education establishments and civil society organisations, to help promote healthy choices and to make them easy and affordable choices. A Union approach will be developed and shared to promote investment in active mobility infrastructures, healthy canteens and to develop outreach measures. Targeted activities of the initiative will complement major Union initiatives, including the European Week of Sport, the EU school scheme, and the EU promotion policy for agri-food products, as well as the Action Plan for the Development of Organic Production⁷.

D – Expected results and impact

The expected results include:

- a) The creation of healthy school environments that promote healthy lifestyles with a spillover effect on the whole community;
- b) The broadening of cross-sectoral cooperation to promote healthy lifestyles across generations;
- c) The investment in a healthy school environment, including healthy canteens.

The action will help to improve healthy lifestyles of children and young people and consequently reduce the incidence of NCDs and reduce their impacts on healthcare systems and social care systems, and ensure the growth and competitiveness of the economy by ensuring a healthy workforce.

E – Specific mandatory deliverables and/or milestones

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

-

⁷ COM(2021)141 final.

The activities will encourage and support schools and other educational settings to adopt the concept of healthy schools — also known as health-promoting schools, and will collect, develop, endorse and share evidence-based practices. The best practices should be in line with the "best practice criteria⁸".

The best practices should be disseminated and implemented through networks of healthy schools. The best practices should be complementary to other ongoing European and national initiatives, focusing on successful practices on health literacy and healthy lifestyles in schools. The applicant is required to set up a consortium of national experts/ professionals having profound knowledge and experience of the concept of healthy schools. It should also build on existing initiatives and school networks. Emphasis of this project will be on the long-term engagement and sustainability of the actions implemented.

The best practices should address most of these areas:

- Regular physical activity including methodologies to measure children's physical fitness
- Food and nutrition with a view to increasing the currently low uptake of fruit and vegetables among children
- Work to ensure that school canteens and cafeterias are designed to encourage children to choose healthier snacks and meals, in line with school national dietary recommendations and food-based dietary guidelines⁹, including technical assistance to intervene and transform the school environment (layout of the canteens, making them smart, inexpensive, attractive and healthier)
- Assessment of the training needs of school staff including the knowledge of school cooks of healthy diets
- Awareness campaigns with social influencers at schools, nudging kids to healthy lives, improvements for vending and items they contain, reducing ads for junk food in the vicinity of schools, strategies and activities to include school staff, children and their parents in the school approach.
- Promotion of healthy lifestyles with a specific focus on tackling childhood obesity and other key risk factors
- Mental health and well-being
- Overarching objective of focus on vulnerable groups/reducing health inequalities

F – Specific action-level indicators for reporting purposes

Applicants must include data on the following indicators in their regular reporting activities in case of award, and must be prepared to include additional specific indicators where needed:

- Number of Member States involved in the funded actions
- Number of regional and local governments
- Number of civil society organisations, including youth organisations
- Number of schools /educational settings involved in the implementation of best practices (divided by primary, secondary or other educational settings).
- Number of pupils/ students involved in the funded actions brokend down by age.
- Number of people who indicate that they would agree to change their health behaviour and

See here the best practice criteria for example: https://ec.europa.eu/health/sites/default/files/major_chronic_diseases/docs/sgpp_bestpracticescrit eria en.pdf

Food-Based Dietary Guidelines in Europe - table 1 | Knowledge for policy (europa.eu)

EUR 4 400 000
Up to three proposals

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 24-36 months.

Part B – Special requirements for this call topic

Examples of Applicants The applicants' profile and institutional type could be the ones listed in the column to the right. Other types of applicants will be also accepted.	Applicant must be able to prove their ability to involve both the education and health sector and to get commitments from responsible local/regional/national authorities.
Applicants – consortium composition	Applications by either a sole applicants or by a consortium are acceptable
Non-eligible activities	Exclude regular procurement funding (e.g. food purchases by schools), but not one-time equipment purchases.
Financial support to third parties	N/a
Place of implementation	N/a
Ethics/Security measures	N/a
Applicants – specific eligibility criteria	Applicant must be able to prove their ability to involve both the education and health sector and to get commitments from responsible local/regional/national authorities.
Specific eligibility criteria applicable to the consortium composition	Applications by either a sole applicants or by a consortium are acceptable
Non-eligible activities	Exclude regular procurement funding (e.g. food purchases by schools), but not one-time equipment purchases.
Financial support to third parties	
Place of implementation	Do you require the project activities to be implemented solely in specifically identified countries?
Ethics/Security measures	Does your call potentially have an impact on ethics rules related to research or does it imply

sensitive information?
No

2.5 Topic EU4H-2021-PJ-10

Action grants to reduce liver and gastric cancers caused by infections

A – Background and policy context

Europe's Beating Cancer Plan aims to ensure access to vaccination against Hepatitis B and to treatments to prevent liver and gastric cancers associated with the Hepatitis C virus and *Helicobacter pylori* infections, respectively. According to the European Centre for Disease Prevention and Control (ECDC)¹⁰, when compared with 2011, the mortality rate in 2015 for all cases of hepatocellular carcinoma increased by 5.3%, and progress towards the 2030 elimination target of a 65% reduction in mortality from the 2015 baseline is currently sub-optimal. Gastric cancer associated with *Helicobacter pylori* infection show important gaps in incidence across the Union. Moreover, there is an acute need to address the risk of liver cancer associated with these specific infections.

The action supports the implementation of the Europe's Beating Cancer Plan objective to prevent cancers caused by infections 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) and (j).

B - Objectives pursued

The action aims to reduce the risk of liver cancers associated with infections caused by the Hepatitis B and Hepatitis C viruses and the risk of gastric cancers caused by *Helicobacter pylori*.

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

Each of the three types of infectious agents will be addressed by specific approaches targeted to support vaccination in case of Hepatitis B virus and to drug treatment in case of Hepatitis C virus and *Helicobacter pylori*. Specific activities will be dedicated to the early detection of infections, the cornerstone strategy to reduce the risk of liver and gastric cancer caused by the three mentioned pathogens.

D – Expected results and impact

Reduction of incidence of Hepatitis B infections and chronic diseases and reduction of Hepatitis C and *Helicobacter pylori* related liver and gastric cancers, respectively.

E – Specific mandatory deliverables and/or milestones

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

The activities will include support to link the existing bodies active in promoting and implementing community wide programmes for early identification of HBV and HCV. In addition, activities will target the networking of clinical centres working in areas where high incidence of *Helicobacter pylori* has been demonstrated, or needs further assessment.

¹⁰ <u>Technical Report, Monitoring the responses to Hepatitis B and C epidemics in EU/EEA Member States, 2019.</u>

F – Specific action-level indicators for reporting purposes

Applicants must include data on the following indicators in their regular reporting activities in case of award, and must be prepared to include additional specific indicators where needed:

Number of initiatives/actions targeted to support early identification of HBV asymptomatic infections.

Number of initiatives/actions targeted to support early identification of HCV asymptomatic infections.

Number of initiatives/actions targeted to support early identification of *Helicobacter pylori* infections symptomatic and asymptomatic).

Number of measures introduced to follow-up positive cases for HBV infections.

Number of measures introduced to follow-up positive cases for HCV infections.

Number of measures introduced to follow-up positive cases for *Helicobacter pylori* infections.

Number of types of material produced for disseminating expertise, best practices, and guidelines (e.g. studies, reports, handbooks, brochures...).

Number of countries/organisations/individuals reached by the funded actions

G – Budget	
Available budget for this topic:	EUR 2 000 000
Proposals to be awarded under this topic:	Up to two proposals – One targeted to HBV and HCV and one targeted to <i>Helicobacter pylori</i>
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.

Part B – Special requirements for this call topic

Examples of Applicants The applicants' profile and institutional type could be the ones listed in the column to the right. Other types of applicants will be also accepted.	N/a
Applicants – consortium composition	Applications by either a sole applicants or by a consortium are acceptable
Non-eligible activities	N/a
Financial support to third parties	N/a
Place of implementation	N/a
Ethics/Security measures	None in addition to the ethics rules already applicable in relation to clinical activities, including diagnosis and treatment, and to the GDPR legislation.
Applicants – specific eligibility criteria	No

Specific eligibility criteria applicable to the consortium composition	Applications by either a sole applicants or by a consortium are acceptable
Non-eligible activities	No
Financial support to third parties	No
Place of implementation	No
Ethics/Security measures	None in addition to the ethics rules already applicable in relation to clinical activities, including diagnosis and treatment, and to the GDPR legislation.

2.6 Topic EU4H-2021-PJ-11

Action grants for 'EU Cancer Treatment Capacity and Capability Mapping' project - Network of Comprehensive Cancer Centres

A – Background and policy context

The European Guide on Quality Improvement in Comprehensive Cancer Control recommends as a priority the establishment of Comprehensive Cancer Care Networks, and likewise the Horizon Europe Cancer Mission Board recommends the establishment of such structures in all Member States as well as the networking of these centres at Union level.

One of the flagship initiatives of Europe's Beating Cancer Plan is the establishment by 2025 of an EU Network linking recognised National Comprehensive Cancer Centres in every Member State to facilitate the uptake of quality-assured diagnosis and treatment, in agreement with the European guidelines and quality assurance schemes for population based screening programmes, including training, research and clinical trials across the Union. The Cancer Plan aims to ensure that 90% of eligible patients have access to such centres by 2030.

This action supports the implementation of a flagship initiative of Europe's Beating Cancer Plan objective to deliver higher-quality care and links also with the European Health Data Space and the European Digital Cancer Patient Centre, and implements the EU4HealthProgramme'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 (g) of Regulation (EU) 2021/522.

B – Objectives pursued

The 'EU Cancer Treatment Capacity and Capability Mapping' action aims to map and share the different capabilities and expertise available across the Union.

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

The action will support the identification of the different capabilities and expertise available across the Union, and build the foundation to regularly identify gaps and needs to be addressed at national and regional level across the Union. At the same time, the EU Network of Comprehensive Cancer Centres will be updated on cancer care innovation as well as on cancer workforce training.

D – Expected results and impact

The mapping of EU Cancer Treatment Capacity and Capability in the Member States is expected to result in facilitating the delivery of higher-quality care and reduce inequalities across the Union,

while enabling patients to benefit from diagnosis and treatment close to home.

E – Specific mandatory deliverables and/or milestones

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

Not applicable.

F – Specific action-level indicators for reporting purposes

Applicants must include data on the following indicators in their regular reporting activities in case of award, and must be prepared to include additional specific indicators where needed:

- Number of inputs treated by the scanning exercise.
- Number (including types) of regular reports provided by the horizon scanning tool(s) developed and operated by the project.
- Number (including types) of downloads of reports.
- Number (including types) of topics identified, selected and prioritised to be included and followed up by the activities implemented in the context of the Comprehensive Cancer Infrastructures.

G –	Bud	get
-----	-----	-----

Available budget for this topic: EUR 1 200 000

Proposals to be awarded under this topic: One 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 24 months.

Part B – Special requirements for this call topic

Examples of Applicants The applicants' profile and institutional type could be the ones listed in the column to the right. Other types of applicants will be also accepted.	N/a
Applicants – consortium composition	Applications by either a sole applicants or by a consortium are acceptable
Non-eligible activities	N/a
Financial support to third parties	N/a
Place of implementation	N/a
Ethics/Security measures	N/a
Applicants – specific eligibility criteria	No
Specific eligibility criteria applicable to the consortium composition	Applications by either a sole applicants or by a consortium are acceptable
Non-eligible activities	No

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

2.7 Topic EU4H-2021-PJ-12

Action grants to create a 'Cancer Survivor Smart Card'

A – Background and policy context

Evidence shows that cancer survivors often report difficulties in communicating with oncologists, general practitioners and nurses, and to establish a link with social services, which can be of particular importance to reduce the risk of negative quality-of-life outcomes. Therefore, it is imperative to develop interventions to improve communication between survivors, health and social care providers. The action will be implemented taking into account the assumption that communication between patients and clinicians embraces three core attributes of 'patient-centered' care: (1) consideration of patients' needs, perspectives, and individual experiences; (2) provision of opportunities to patients to participate in their care ('self-management'); and (3) enhancement of the patient-clinician-nursing relationship.

This action supports the implementation of Europe's Beating Cancer Plan objective to improve the quality of life for cancer patients, survivors and carers and links with the European Health Data Space and the European Cancer Patient Digital Centre, 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), (f) and (g) of Regulation (EU) 2021/522.

B – Objectives pursued

The aim of the action is to improve the quality of life and health status of cancer survivors, and to address their potential needs through the development and support for the wide use of new approaches to communication.

A 'Cancer Survivor Smart Card' will link with a 'resource' function to give access to best practices, guidelines and recommendations specifically targeted to cancer survivors, with a view to helping them to address or to connect with professionals in different areas, to deal with the most common issues that survivors face, such as insufficient management of late and long-term effects of treatment, unmet psychosocial needs, self-management, pain management, and issues related to rehabilitation, emotional distress, tumour recurrence and metastatic disease.

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

The action will support the development, delivery and usability of a personalised 'Cancer Survivor Smart Card' by 2022. The smart card, in the form of an interoperable portable eCard or app, will store certain information related to the monitoring and follow-up of the survivor, including the survivor's clinical history and follow-up. The smart card will allow connection with the health professionals responsible for the individual's follow-up, including the survivor's general practitioner, to improve healthcare provider and survivor communication on the survivor's worries, questions and other matters of relevance to improve the survivor's quality of life. The action will involve patients' groups and health and social care providers, in order to apply a participatory and co-creative approach to help with the development of the tool, and to coach a group of 'card-users' to pilot the smart card's usage once it has been developed, in preparation for the wider application

phase.

D – Expected results and impact

The co-creation, piloting, promotion, and use of the 'Cancer Survivor Smart Card' is expected to improve patient-centred communication between cancer survivors and health and social care providers, through the wide use of communication tools and the application of new approaches to communication to improve quality of life, promote healing and reduce suffering.

This is likely to improve the quality of life of cancer patients, including that of children and young cancer survivors, through dissemination of best practices on issues such as psychological support, self-management, pain management and professional re-integration. The action will also facilitate the portability and the sharing of data from medical records.

The action will ensure a shared and equal access to high-quality information and data, and best practices for cancer survivors across the Union. No country can reach the same results alone, in particular considering that survivorship is still an area that requires additional evidence-based information, and that a shared approach will ensure the improvement of the quality of life of cancer survivors.

E – Specific mandatory deliverables and/or milestones

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

Participants in the action have to regularly report on the progress of the development, delivery and usability of the Card.

F – Specific action-level indicators for reporting purposes

Applicants must include data on the following indicators in their regular reporting activities in case of award, and must be prepared to include additional specific indicators where needed:

- Number of participants involved to pilot the Cancer Survivor Smart Card (breakdown per country, gender and socioeconomic status).
- Estimated number of people who indicated that the Card has improved the communication with their health and social care providers (breakdown per country, gender and socioeconomic status).
- Number of supportive (online) materials for cancer survivors produced and disseminated (breakdown per breakdown per country and target group).
- Number of (validated) best practices identified, collected and shared.

G – Budget

Available budget for this topic: EUR 1 800 000 Proposals to be awarded under this topic: one 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 24 months.

Part B – Special requirements for this call topic

Examples of Applicants	Academia and education establishments, civil
The applicants' profile and institutional type	,

could be the ones listed in the column to the right. Other types of applicants will be also accepted.	society organisations (associations, foundations, NGOs and similar entities), and research institutes in the field of public health having experience in information, communication and inequalities.
Applicants – consortium composition	N/a
Non-eligible activities	N/a
Financial support to third parties	N/a
Place of implementation	N/a
Ethics/Security measures	None in addition to the ethics rules already applicable in relation to the GDPR legislation.
Applicants – specific eligibility criteria	Academia and education establishments, civil society organisations (associations, foundations, NGOs and similar entities), and research institutes in the field of public health having experience in information, communication and inequalities.
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	None in addition to the ethics rules already applicable in relation to the GDPR legislation.

2.8 Topic EU4H-2021-PJ-13

Action grants to support the implementation of best practices in community-based services for the human immunodeficiency virus (HIV) infection and acquired immunodeficiency syndrome (AIDS), tuberculosis, viral hepatitis and sexually transmitted infections

A – Background and policy context

Communicable diseases such as HIV/AIDS, tuberculosis, viral hepatitis and sexually transmitted infections are examples of epidemics that continue to beset our societies, posing a public health burden. In addition, major communicable diseases can be serious cross-border health threats, with the potential to rapidly escalate, if left unchecked. HIV, tuberculosis and viral hepatitis, in particular, remain a challenge to Member States' health systems. Moreover, the Union is not yet on track to reach the United Nations Sustainable Development Goals, including ending HIV and tuberculosis,

and combatting viral hepatitis by 2030. In 2016, the Commission committed itself to support Member States in reaching these targets¹¹.

There is wide recognition (including by ECDC, UNAIDS and WHO) that community responses must play an increasing role in addressing the epidemics and many Member States include community-based services in their response. Further support is needed to broaden the reach of services, supporting retention in care, increasing demand, monitoring quality, advancing human rights and combatting stigma and discrimination.

This action supports the prevention and monitoring of communicable diseases and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3, point (a)) through the specific objectives in Article 4, points (a), (b) and (j) of Regulation (EU) 2021/522.

B - Objectives pursued

The action aims at strengthening and supporting community-based service organisations in the Member States and neighbouring countries in the implementation of people-centre effective and integrated interventions, as well as linkage to care amongst groups at high risk of contracting HIV/AIDS, tuberculosis, viral hepatitis and sexually transmitted infections. It will also directly contribute to national programmes and public health measures, thus, supporting the implementation of internationally agreed goals.

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

The action will build on the results of the Third Health Programme (2014-2020), which, among others, served to foster the development of integrated community-based services, the setting-up of Union-wide networks and the design of tools/guides for community-based services.

This action will support the implementation of the generated knowledge, as well as piloted good practices.

Activities shall include one or more of the below topics:

- (a) the strengthening and expansion of community voluntary testing, early diagnosis and linkage to care of HIV/AIDS, tuberculosis, viral hepatitis and sexually transmitted infections as well as counselling. They will also pursue harm-reduction, peer support, prison-in-reach and through-care services approaches in hard-to-reach vulnerable groups;
- (b) the implementation and scaling up of tools developed under previous actions and other practical approaches to support community-based activities. This will include implementation and quality assurance of Union-wide standardised indicators on testing and linkage to care and treatment among key risk groups;
- (c) consolidation of the existing network(s) of community-based services in Europe in order to forge closer interaction, facilitate the exchange of best practice and promote innovative approaches fostering the increase of early diagnosis of HIV/AIDS, tuberculosis, viral hepatitis and sexually transmitted diseases and linkage to care in Europe among the most affected groups.

D – Expected results and impact

The expected results are:

_

Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Next steps for a sustainable European future: European action for sustainability, COM(2016) 739 final, 22.11.2016.

- a) integrated community-based health services, including prevention, counselling, peersupport, harm-reduction, prison-in-reach and through-care services, as well as testing and linkage to care;
- b) capacity and network building in the areas of HIV/AIDS, hepatitis and tuberculosis, including training, promotion and use of relevant IT tools towards hard-to-reach populations;
- c) horizontal support tasks including organisation of meetings and exchange of information facilitating the participation of relevant civil society organisations and networks.

E – Specific mandatory deliverables and/or milestones

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

The applicants should indicate in the proposal the reasoning and criteria for choosing the respective Good/Best Practices and/or tools/guides for implementations.

Networks are encouraged as much as possible to work together across diseases (instead of focusing on one disease only) and to foster an integrated, and people oriented approach. For all activities:

- Dissemination plan and report;
- Evaluation plan and report;

For activities (a) and (b):

- Implementation report, outlining the strength and weaknesses of the transfer/scaling up of the best practices and/or implementation of tools/guides (including lessons learned, recommendations for future transfers/scaling up, monitoring of impact);

For activity (c):

- Annual activity report, outlining the implemented changes to the network during the reporting period and the achievements of the network done during the reporting period (including lessons learned, recommendations for future transfers/scaling up, monitoring of impact);

F – Specific action-level indicators for reporting purposes

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

For Activity (a):

- Number of patients being tested in the community settings under funded activities;
- Percentage of patients being tested under funded activities, with respect to total patients tested in the community settings;
- Number of patients having received prevention, counselling, peer-support, harm-reduction or through-care services under funded activities;
- Percentage of patients having received services under funded activities under funded activities, with respect to total patients having received prevention, counselling, peer-support, harm-reduction or through-care services under funded activities;

For Activity (b):

- Uptake of existing tools and guide (downloads, citations);
- Patients/Citizens reached by the tools/guides, under funded activities;

For Activity (c):

- Number of new membership of the network;
- Patients/persons reached with the network activities, under funded activities;
- Additional Health- and health care professionals reached under funded activities;
- Funded activities satisfaction rate of patients, community, health- and health care providers

G – Budget

Available budget for this topic: EUR 5 000 000

Proposals to be awarded under this topic: 1-5 Project Grants

H – Expected duration of project

Given the complexity of the activities to be funded under this topic, the indicative length of a project is 36 months.

Part B – Special requirements under this call topic

	Applicant organisations interested in applying shall fulfil the following eligibility criteria:
	Civil society organisations (associations, foundations, NGOs and similar entities
Examples of Applicants The applicants' profile and institutional type could be the ones listed in the column to the right. Other types of applicants will be also accepted.	2. The applicant organisation(s) has to have activities related to the prevention, outreach and awareness raising, public health support services, community services and/or other similar activities aimed at reducing the transmission or improving the quality of life of people living with HIV/AIDS, viral hepatitis (B and/or C) and/or tuberculosis as a main focus of its work.
	The applicant organisations would ideally belong to one or more of the following categories:
	 Organisations working in/with affected communities or key at-risk populations;
	 Regional networks/ umbrella organisations.
	Applications by either a sole applicants or by a consortium are acceptable
Applicants – consortium composition	The applicant organisations shall have the necessary geographical coverage and outreach, specifically for activities (a) and (b).
Non-eligible activities	N/a
Financial support to third parties	N/a
Place of implementation	N/a

Ethics/Security measures	National regulations on ethics approval shall apply.
	Applicant organisations interested in applying shall fulfil the following eligibility criteria:
	4. Civil society organisations (associations, foundations, NGOs and similar entities
Applicants – specific eligibility criteria	5. The applicant organisation(s) has to have activities related to the prevention, outreach and awareness raising, public health support services, community services and/or other similar activities aimed at reducing the transmission or improving the quality of life of people living with HIV/AIDS, viral hepatitis (B and/or C) and/or tuberculosis as a main focus of its work.
	6. The applicant organisations would ideally belong to one or more of the following categories:
	 Organisations working in/with affected communities or key at-risk populations;
	 Regional networks/ umbrella organisations.
	Applications by either a sole applicants or by a consortium are acceptable
Specific eligibility criteria applicable to the consortium composition	The applicant organisations shall have the necessary geographical coverage and outreach, specifically for activities (a) and (b).
Non-eligible activities	N/A.
Financial support to third parties	Yes, if well justified and necessary for the action.
Place of implementation	Participating countries.
Ethics/Security measures	National regulations on ethics approval shall apply.

2.9 Topic EU4H-2021-PJ-14

Action grants supporting training activities, implementation, and best practices – EU One Health Action Plan against antimicrobial resistance

A – Background and policy context

Antimicrobial resistance (AMR) – the ability of microorganisms to resist antimicrobial treatments, especially antibiotics – has a direct impact on human and animal health and carries a heavy economic burden due to higher costs of treatments and reduced productivity caused by sickness. AMR is responsible for an estimated 33 000 deaths per year in the Union. It is also estimated that

AMR costs in the Union amount to €1.5 billion per year in healthcare and productivity losses.

In June 2017, the Commission adopted the EU One Health Action Plan against AMR. With its holistic view on the issue, recognising the link between human and animal health and the role of the environment, it has three key objectives: making the Union a best practice region, boosting research development and innovation and shaping the global agenda. As part of the first objective, the plan pursues a better prevention and control of AMR, among other things, by strengthening infection prevention and control measures. As indicated in the plan, the Commission will help to address patient safety in hospitals and long term care facilities by supporting good practices in infection prevention and control.

The mission letter to Commissioner Stella Kyriakides defines the need to tackle the rise or return of highly infectious diseases, highlighting the need to focus on the full implementation of the EU One Health Action Plan against AMR in order to work with international partners to advocate for a global agreement on the use of and access to antimicrobials.

The action supports the policy priority to prevent and control the rise or return of highly infectious diseases. It implements the EU4Health Programme's general objective of protecting people in the Union from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination among the Member States in order to cope with serious cross-border threats to health (Article 3, point (b)) through the specific objectives defined in Article 4, points (a), (b) and (i) of Regulation (EU) 2021/522.

B – Objectives pursued

This action aims to support enhanced hospital and long-term care facilities infection prevention and control practices, as well as antimicrobial stewardship practices, and the development of best practices and implementation at all levels. It supports the commitment in the EU One Health Action Plan against AMR for the Commission to help to address patient safety in hospitals by supporting good practices in infection prevention and control and antimicrobial stewardship.

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

The activities will focus on capacity building, by providing training and implementation of enhanced infection prevention and control (IPC) practices and antimicrobial stewardship (AMS) in hospitals and in long-term care facilities and support for further dissemination, as well as AMS in primary care.

They shall include training as well as other activities to support good practice in IPC, and AMS including clinical audit and feedback, action by regulators (e.g. incentive schemes, sanction schemes), pilots to showcase state-of-the-art IPC and AMS schemes in hospitals and long term facilities that can be replicated elsewhere using for instance the Cohesion Policy funds in the future (e.g. for investments into healthcare infrastructure).

D – Expected results and impact

The support of capacity building is expected to enhance primary and secondary healthcare services. An improved effectiveness of healthcare systems to prevent infection is likely to result in reductions in healthcare associated infections and improvements in patient safety in relation to AMR in the participating hospitals and long-term care facilities.

E – Specific mandatory deliverables and/or milestones

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

Developed best practice and considerations/plan for its wider uptake (e.g. pilot accompanied by a replication plan) and developed trainings.

- Dissemination Plan and Report;
- Evaluation Plan and Report.

F – Specific action-level indicators for reporting purposes

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

Capacity building activities

- Number of training courses organized implementation
- Number of specialists trained output
- Satisfaction rate of trainees direct result
- Number of trainees having introduced new practice at work after the training (to be considered when the N. of trainees is limited) indirect result

Best practices

- Number of structures involved (hospitals, long-term care facilities...) implementation
- Number of best practice case studies developed output
- Number of outreach events organised output
- Number of structures declaring to have introduced best practices result

G - Budget

Available budget for this topic: EUR 7 000 000

Proposals to be awarded under this topic: Up to 5 projects

H – Expected duration of project

Given the complexity of the activities to be funded under this topic, the indicative length of a project is 36 months.

Part B – Special requirements to be included in the call document

Examples of Applicants The applicants' profile and institutional type could be the ones listed in the column to the right. Other types of applicants will be also accepted.	N/a
Applicants – consortium composition	A consortium composed of at least 3 applicant organisations established in at least 3 different eligible countries
Non-eligible activities	N/a
Financial support to third parties	N/a

Place of implementation	N/a
Ethics/Security measures	Applicable national regulations shall apply.

2.10 Topic EU4H-2021-PJ-15

Action grants for 'Cancer Diagnostic for Public Health'

A - Background and policy context

Cancer is strongly driven by genomic modifications, and new technological approaches are now available for diagnostic, therapeutic and personalised risk-assessment for prevention. These new approaches have a relevant positive impact on the outcome of cancer care. Therefore, there is a need to support access to such measures while guaranteeing a viable and a high standard of performance of these new techniques.

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

B – Objectives pursued

The new 'Cancer Diagnostic and Treatment for All' initiative, and the 'Genomic for Public Health' project will help Member States to improve access for individuals and cancer patients and survivors to prevention, diagnosis and treatment of cancer through personalised medicine, by upscaling available innovation (12) in the field of innovative cancer diagnosis and treatment.

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

Applicants shall target their proposal to one or both of the action subtopics (a, b) described below and indicate that clearly in the proposal.

Sub-topic (a) - - 'Cancer Diagnostic and Treatment for All' initiative: It will use the 'next generation sequencing' technology for a quick and efficient application of personalised cancer diagnosis and treatment. The action will scale up the already available results in genetic profiling of patients and tumour cells allowing cancer centres to share such cancer profiles with a view to apply the same or similar diagnostic and therapeutic approaches to patients with comparable cancer profiles across the Union.

Sub-topic (b) - 'Genomic for Public Health' project: which is expected, to scale up the '1+ Million Genome Initiative' results, to translate them into implementable public health measures to address cancer prevention on the basis of specific individual genetic profiles, which indicates the susceptibility of individuals to develop a certain type of cancer. Therefore, the project will open new perspectives to personalised risk-assessment and targeted cancer prevention.

D – Expected results and impact

The 'Cancer Diagnostic and Treatment for All' and the 'Genomic for Public Health' actions will help Member States to develop guidelines and recommendations to better determine who and what to test, organise health services to implement genetic testing, and provide specific education and training for health workers to advance our understanding of cancer control. Ultimately, individuals

For example, from OncGNS: Next Generation Sequencing diagnostics in 21st century oncology: the best, for all, at all times.

and cancer patients will benefit on a large-scale of a high quality and viable way to prevent cancer, to diagnose and treat it.

E – Specific mandatory deliverables and/or milestones

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

No

F – Specific action-level indicators for reporting purposes

Applicants must include data on the following indicators in their regular reporting activities in case of award, and must be prepared to include additional specific indicators where needed:

Sub-topic (a) - 'Cancer Diagnostic and Treatment for All' project

- Number and type of available 'next generation sequencing' technology proposed for application of personalised cancer diagnosis and treatments.
- Number of cancer centres, which are skilled and are offering 'next generation sequencing' technology for application of personalised cancer diagnosis and treatment.
- Member States and Regions that have a capacity to offer 'next generation sequencing' technology for application of personalised cancer diagnosis and treatment.
- Number of patients who have benefitted from 'next generation sequencing' technology for personalised cancer diagnosis and treatment.

Sub-topic (b) - 'Genomic for Public Health' project

- Number and type of implementable public health measures to identify individual genetic profiles, indicating susceptibility of individuals to develop a certain type of cancer.
- Number of cancer centres, which are skilled and routinely offering approaches and measures to identify individual genetic profiles, indicating susceptibility of individuals to develop a certain type of cancer.
- Member States and Regions that have the capacity to offer approaches and measures to identify individual genetic profiles, indicating susceptibility of individuals to develop a certain type of cancer.
- Number of patients who have benefitted from approaches and measures to identify individual genetic profiles, indicating susceptibility of individuals to develop a certain type of cancer.

G – Budget

Available budget for this topic:

EUR 3 000 000 for strand a)

EUR 3 000 000 for strand b)

Proposals to be awarded under this topic: Up to two proposals

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.

Part B – Special requirements for this call topic

Examples of Applicants	N/a
The applicants' profile and institutional type	
could be the ones listed in the column to the	

right. Other types of applicants will be also accepted.	
Applicants – consortium composition	Applications by either a sole applicants or by a consortium are acceptable
Non-eligible activities	N/a
Financial support to third parties	N/a
Place of implementation	N/a
Ethics/Security measures	None in addition to the ethics rules already applicable in relation to clinical activities, including diagnosis and treatment, and the GDPR legislation.
Applicants – specific eligibility criteria	No
Specific eligibility criteria applicable to the consortium composition	Applications by either a sole applicants or by a consortium are acceptable
Non-eligible activities	No
Financial support to third parties	No.
Place of implementation	No.
Ethics/Security measures	None in addition to the ethics rules already applicable in relation to clinical activities, including diagnosis and treatment, and the GDPR legislation.

2.11 Topic EU4H-2021-PJ-16

Action grants for the Computer-aided Drug Repurposing for Cancer Therapy Project

A – Background and policy context

Despite huge improvements, current anticancer pharmacological therapies are effective in a limited number of cancer cases. Tumours with a high mortality rate, a target not reachable by chemotherapy, and chemotherapy resistance, represent the current challenges of cancer treatments. As the pharmaceutical productivity and drug efficacy in oncology seem to have reached a plateau, 'drug repurposing' — meaning the use of old drugs, already in clinical use, for a different therapeutic indication, is a promising and viable strategy to improve cancer therapy. Opportunities for drug repurposing are often based on occasional observations or on time-consuming pre-clinical drug screenings that are often not hypothesis-driven.

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

B – Objectives pursued

The aim of the action is to identify potential viable effective anti-cancer drugs by making use and piloting 'in-silico drug repurposing' including by upscaling available innovation¹³ using advanced computing and the new big-data technologies and high-performance computing while reducing timeframes and development costs.

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

The action will launch an EU platform based on 'computational drug networks' to predict, in-silico, the efficacy of approved drugs against relevant cancer targets, as well as to select better responder patients or disease biomarkers. This will be implemented following a time and cost-effective approach, also building on experiences with repurposing of medicines to treat COVID-19, where high-performance computing will be used to rapidly test existing molecules and new drug combinations.

The action will also devise and test models for closer collaboration among stakeholders.

D – Expected results and impact

The launch of an EU platform based on improved 'computational drug networks' is expected to result in a better prediction of the efficacy of approved drugs against relevant cancer targets, as well as to select better responder patients or disease biomarkers, and to link Member States' structures responsible for cancer treatment and care.

Starting with cancers with poor prognosis and rare cancers, and using high-performance computing, this work will help to improve the arsenal of anticancer drugs and overcome certain limitations of modern cancer therapies against old and new therapeutic targets in oncology.

The action is likely to increase available anticancer drugs and overcome limitations of current cancer therapies against old and new therapeutic targets in oncology, to the final benefit of patients with poor prognosis and rare cancers.

E – Specific mandatory deliverables and/or milestones

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

- Development of a concept for drug re-purposing in the field of cancer care with focus on innovative computer aided approaches. Specific attention to be given to areas that will benefit patients with cancers with poor prognosis and rare cancers. The work has to build on existing experiences and concepts (globally) and link in particular with efforts to 'Building a European innovation platform for the repurposing of medicinal products'¹⁴
- Proof of concept and piloting of the approach.
- Concept for the sustainable establishment of an EU platform and recommendations for further development work.

F – Specific action-level indicators for reporting purposes

Applicants must include data on the following indicators in their regular reporting activities in case of award, and must be prepared to include additional specific indicators where needed:

¹³ For example from HORIZON-HLTH-2021-DISEASE-04-02: *Building a European innovation platform for the repurposing of medicinal products.*

¹⁴ HORIZON-HLTH-2021-DISEASE-04-02

- number of innovative computer aided approaches considered.
- number of events, meetings and discussions organised.
- number of participants (Member State, other countries or international organisations).
- number of medicinal products tested.

G - Budget

Available budget for this topic: EUR 3 000 000

Proposals to be awarded under this topic: One single proposal, or up to 2.

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 24-36 months.

Part B – Special requirements for this call topic

Examples of Applicants The applicants' profile and institutional type could be the ones listed in the column to the right. Other types of applicants will be also accepted.	N/a
Applicants – consortium composition	Applications by either a sole applicants or by a consortium are acceptable, but sole applicants or lead partners of a consortium need to provide proof of having prior relevant experience in the field concerned
Non-eligible activities	N/a
Financial support to third parties	N/a
Place of implementation	Inside EU/EEA countries
Ethics/Security measures	N/a
Applicants – specific eligibility criteria	
Specific eligibility criteria applicable to the consortium composition	Applications by either a sole applicants or by a consortium are acceptable, but sole applicants or lead partners of a consortium need to provide proof of having prior relevant experience in the field concerned
Non-eligible activities	
Financial support to third parties	N/A
Place of implementation	Inside EU/EEA
Ethics/Security measures	N/A

2.12 Topic EU4H-2021-PJ-17

Action grants to organise and collect data to understand the safety, quality and efficacy of therapies applied in the field of assisted reproduction and therapies based on haematopoietic stem cells

A – Background and policy context

Hematopoietic stem cells play a significant role in the area of cancer immunotherapy, in particular in the treatment of liquid blood cancers like leukaemia and lymphoma.

Medically assisted reproduction (MAR) is a field of major and increasing importance, where shortcomings have been identified related to the protection of donors and offspring. In addition, MAR can also play a direct role in cancer care by sustaining fertility of young patients by preserving their reproductive cells for use in MAR after cancer treatment that would have rendered them infertile.

The action supports the policy priority to respond to the COVID-19 crisis and 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 as defined in (Article 3, point (c)) through the specific objectives defined in Article 4, point (c) of Regulation (EU) 2021/522.

B - Objectives pursued

This action will aim to collect and organise in registries data on the safety, quality and efficacy of therapies applied in the field of medically assisted reproduction (MAR) and haematopoietic stem cell transplantation.

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

This action will support Union data collection, aggregation and analysis on the use and outcome of therapies in the fields of:

- (a) assisted reproduction;
- (b) haematopoietic stem cells.

For both (a) and (b) it will facilitate the design, development and management of dedicated IT solutions with and for medical/healthcare professionals.

D – Expected results and impact

The expected results are new or substantially upgraded digital registries with higher quality data entries from medical professionals across the Union and Member States authorities. This will provide good quality data collection on therapies in the field of MAR and based on haematopoietic stem cells and facilitate data sharing for open science and for Union legal requirements for oversight purposes, for monitoring safety and outcome as well as for the protection of donors and offspring.

Proposed solutions should ensure the findability, accessibility, interoperability, and reuse of digital assets (FAIR principles), use or interoperate with the main European and global data standards and other initiatives (i.e. European Health Data Space, EOSC Life).

Qualitative data will be available for professionals as well as authorities and other stakeholders in the sector and facilitate their respective tasks in the sector (such as clinical protocols, authorisations, market feedback, value-based reimbursement), while respecting the provisions on

privacy protection (GDPR).

This will allow improving and promoting medical excellence, as well as increasing the efficiency of the healthcare systems and transparency for patients.

The action will have an impact on the digital transformation and uptake of digital solutions in the Union sector of MAR and hematopoietic stem cells, in order to facilitate the monitoring of activities and outcomes.

E – Specific mandatory deliverables and/or milestones

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

- Documentation of the registry, using Unified Modelling Language (UML) including the data model, data flows, use cases and access by/for different stakeholders, in particular competent authorities
- Interoperability plan (use of standard taxonomies, data standards, links to open and European data assets)
- Implementation and investment plan
- Operational and financial plan
- Management and Governance plan, including the role of national competent authorities in the long term sustainability

F – Specific action-level indicators for reporting purposes

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

- Number of professionals/centres participating
- Number of Member States covered
- Number of fields in the database
- Number of records treated by strand
- Number of data note deployed by strand
- Number of data exploited

G – Budget

Available budget for this topic:

EUR 2 000 000 for strand b)

Proposals to be awarded under this topic: One single proposal per strand

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.

Part B – Special requirements for this call topic

Examples of Applicants	Applicants	must	have	their	core
The applicants' profile and institutional type	activities/exp	erience i	n the field	d of	
could be the ones listed in the column to the right. Other types of applicants will be also	(a) assisted r	eproducti	on;		
accepted.	(b) haemato	ooietic ste	em cells.		

	Applicants must have experience with gathering of clinical outcome data within this fields of activity Applicants must have a scope of activity covering more than one EU Member State		
Applicants – consortium composition	Applications may be either by a sole applicant or a consortium (no minimum requirement)		
Non-eligible activities	N/a		
Financial support to third parties	N/a		
Place of implementation	Activities should be implemented within the EU territory		
Ethics/Security measures	Projects must comply with: - highest ethical standards and - applicable EU, international and national law Specific pational rules relating to othics in those		
	Specific national rules relating to ethics in these fields must be respected.		

2.13 Topic EU4H-2021-PJ-18

Action grants boosting cancer prevention through the use of the European Code against Cancer and other concerted actions

A - Background and policy context

About 40% of cancer cases in the Union are preventable. Prevention is also the most cost-efficient long-term cancer control strategy. It is estimated that the cancer burden could be reduced by up to 50% if scientific knowledge on causes of cancer could be translated into successful preventive actions, including through improving health literacy with the view to increasing access to understandable messages on prevention, including by hard-to-reach and marginalised groups of the population.

One of the policy objectives of Europe's Beating Cancer Plan is to improve health literacy on cancer risks and determinants. Initiatives will be launched to give people the information and tools they need to make healthier choices. The European Code against Cancer, which was first published in 1987, has a long-standing tradition as a preventive tool aimed at reducing the burden of cancer by informing people on how to avoid or reduce carcinogenic exposures, adopt behaviours to reduce their cancer risk, or to participate in organised intervention programmes. The European Code against Cancer needs to be updated to take into account the latest scientific developments and to include new evidence-based recommendations to improve health literacy and to guide national health policies in cancer prevention.

Evidence demonstrates that the recommendations of the European Code against Cancer are only partially reaching the general population. Therefore, there is a need to improve its impact across the Union. To achieve this, there is a need for the appropriate tools and instruments to improve communication with the public and to make use of new communication tools, including taking into account a gender-sensitive approach. An 'EU Mobile App for Cancer Prevention' will be developed to extend the coverage of the European Code against Cancer, to help behavioural interventions through commitment devices and reminders, with the aim of empowering people to manage their own health. To ensure that the recommendations of the European Code against Cancer are understood and translated into practice, communication will be adapted according to the literacy level of the target population, as a low health literacy is one of the social determinants of health associated with cancer-related disparities.

This action supports the implementation of a Europe's Beating Cancer Plan flagship initiative 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 (j) of Regulation (EU) 2021/522.

B – Objectives pursued

The aim of this action is to improve access to and understanding of risk factors and health determinants to improve health outcomes for cancer.

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

Applicants shall target their proposal to one or both of the action strands (a, b) described below and indicate that clearly in the proposal.

(a) to support the usability of the recommendations of the European Code against Cancer through the 'EU Mobile App for Cancer Prevention' by means of activities covering training, piloting and promotion amongst the general population. Support will include activities to

- provide relevant input for the design and development of the 'EU Mobile App for Cancer Prevention'.
- (b) to support 'Health Literacy for Cancer Prevention and Care' by means of activities that develop and share best practices to strengthen health literacy in cancer prevention and care programmes, with a focus on disadvantaged groups. These activities will include the assessment of literacy on cancer prevention and will provide support for targeted actions to improve the degree to which individuals have the capacity to obtain, process, and understand health information to make informed decisions about cancer prevention. These targeted actions will be designed taking into consideration health literacy programs developed within healthcare systems and in the community, for instance, to reduce medical jargon and improve education using plain language, easy-to-understand written materials and teach-back, and also plain language written materials, including visuals to provide more culturally and linguistically appropriate health education and enhanced web-based information.

D – Expected results and impact

The expected results are:

- (a) increased usability of 'EU Mobile App for Cancer Prevention' amongst the general population through training, piloting and promotion;
- (b) the launch of a project to increase health literacy for cancer prevention and care.

The action aims to reduce individual cancer risks across the Union through the application of the European Code against Cancer recommendations.

E – Specific mandatory deliverables and/or milestones

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

None

F – Specific action-level indicators for reporting purposes

Applicants must include data on the following indicators in their regular reporting activities in case of award, and must be prepared to include additional specific indicators where needed:

Usability of the App:

- Number of downloads of the App (breakdown per country, gender and education/income level)
- Number of (online) training courses organised (breakdown per country and per target audience, such as school children, elderly, people at work, etc)
- Number of (online) promotional activities organised (breakdown per country)
- Estimated number of people reached (breakdown per country, gender and education/income level)
- Estimated number of people who indicate that the App has improved their knowledge changed their behaviour and lifestyle (breakdown per country, gender and education/income)
- Number of feedback from users (breakdown per country, gender and education/income level) Health literacy project
- Number of best practices identified, collected and shared
- Estimated number of people reached (breakdown per country, gender and education/income level)
- Estimated number of people who indicate that the project has improved their knowledge and changed their behaviour and lifestyle (breakdown per country, gender and education/income)
- Number of cancer organisations and other stakeholders involved in the funded actions

(breakdown per country)

- Number of (online) materials for enhancing health literacy produced and disseminated (breakdown per breakdown per country and target group)
- Number of hits for web-based information (breakdown per country)
- Number of targeted actions to specifically reach and involve vulnerable and disadvantaged population groups (breakdown per country and socio-economic group)

G – Budget	
Available budget for this topic.	EUR 1 500 000 for strand a)
Available budget for this topic:	EUR 1 000 000 for strand b)
Proposals to be awarded under this topic:	Two proposals covering strands a) and b)
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.

Part B – Special requirements for this call topic

Examples of Applicants The applicants' profile and institutional type could be the ones listed in the column to the right. Other types of applicants will be also accepted.	Academia and education establishments, civil society organisations (associations, foundations, NGOs and similar entities), and research institutes in the field of public health having experience in information, communication and inequalities.		
Applicants – consortium composition	Applications by either a sole applicants or by a consortium are acceptable		
Non-eligible activities	N/a		
Financial support to third parties	N/a		
Place of implementation	N/a		
Ethics/Security measures	N/a		

3. Available budget

The available call budget is **EUR 43 850 000**. 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
EU4H-2021-PJ- 06 Action grants for developing a pilot project for an EU infrastructure ecosystem for the secondary use of health data for research, policymaking and regulatory purposes	5.000.000	One single proposal	The duration of proposals should range between 12 and 24 months. Given the existence of preliminary know how in this domain, the expected length of the project could be 18 months.
EU4H-2021-PJ- 07 Action grants to support implementation of best practices on the ground with direct impact on the effort to tackle mental health challenges during COVID-19	750.000	One or two proposals	The duration of proposals should range between 12 and 36 months. Given the existence of preliminary know how in this domain, the expected length of the project could be 24 months.
EU4H-2021-PJ-08 Action grants to support actions to improve access to human papillomavirus vaccination	1.200.000	1 proposal	The duration of proposals should range between 12 and 36 months. Given the complexity of the activities to be funded under this topic, the recommended length of a project is 24 months.
EU4H-2021-PJ-09 Action grants for the initiative 'HealthyLifestyle4All': promotion of healthy lifestyles	4.400.000	Up to 3 proposals	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- 36 months.

EU4H-2021-PJ-10 Action grants to reduce liver and gastric cancers caused by infections	2.000.000	Up to two proposals: One targeted to HBV and HCV and one targeted to Helicobacter pylori	The duration of proposals should range between 12 and 36 months. Given the complexity of the activities to be funded under this topic, the recommended length of a project is 24 months.
EU4H-2021-PJ-11 Action grants for 'EU Cancer Treatment Capacity and Capability Mapping' project - Network of Comprehensive Cancer Centres	1.200.000	One proposal	The duration of proposals should range between 12 and 36 months. Given the complexity of the activities to be funded under this topic, the recommended length of a project is 24 months.
EU4H-2021-PJ-12 Action grants to create a 'Cancer Survivor Smart Card'	1.800.000	One proposal	The duration of proposals should range between 12 and 36 months. Given the complexity of the activities to be funded under this topic, the recommended length of a project is 24 months.
EU4H-2021-PJ-13 Action grants to support the			Given the complexity
implementation of best practices in community-based services for the human immunodeficiency virus (HIV) infection and acquired immunodeficiency syndrome (AIDS), tuberculosis, viral	5.000.000	Up to 5 proposals	Given the complexity of the activities to be funded under this topic, the indicative length of a project is 36 months.

EUAU 2024 DI 44			
Action grants supporting training activities, implementation, and best practices (AMR)	7.000.000	Up to 5 proposals	Given the complexity of the activities to be funded under this topic, the indicative length of a project is 36 months.
EU4H-2021-PJ-15 Action grants for 'Cancer Diagnostic and Treatment for All' including 'Genomic for Public Health'	EUR 3 000 000 for strand a) EUR 3 000 000 for strand b)	Up to two proposals	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.
EU4H-2021-PJ-16 Action grants for the Computer-aided Drug Repurposing for Cancer Therapy Project	3.000.000	One single proposal, or up to 2.	The duration of proposals should range between 12 and 36 months. Given the complexity of the activities to be funded under this topic, the recommended length of a project is 24-36 months.
EU4H-2021-PJ-17 Action grants to organise and collect data to understand the safety, quality and efficacy of therapies applied in the field of assisted reproduction and based on haematopoietic stem cells		EUR 2 000 000 for strand a) EUR 2 000 000 for strand b)	One single proposal per strand

EU4H-2021-PJ-18 Action grants boosting cancer prevention through the use of the European Code against Cancer and other concerted actions	2.500.000	EUR 1 500 000 for strand a) EUR 1 000 000 for strand b)	The duration of proposals should range between 12 and 36 months. Given the complexity of the activities to be funded under this topic, the recommended length of a project is 24 months.
--	-----------	--	--

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:	13 October 2021		
Proposal submission opening:	14 October		
Deadline for submission of proposals:	25 January 2022 - 17:00:00 CET (Brussels)		
Evaluation:	February - May 2022		
Information on evaluation results:	June 2022		
GA signature:	October 2022		

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:

ullet 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 (standard) of core project team
 - activity reports of last year: not applicable
 - list of previous projects (key projects for the last 4 years) (template available in Part B)
 - other 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) created under Union law or an international organisation, or
- 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:

EEA countries and countries associated to the EU4Health Programme (third countries, candidate countries and potential candidate countries, neighbourhood countries) <u>or</u> countries which are in ongoing negotiations for an association agreement and where the agreement enters into force before grant signature.

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

Other entities may participate in other consortium roles, such as associated partners, subcontractors, etc. (see section 13).

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 persons¹⁵.

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

Associations and interest groupings — Entities composed of members may participate as 'sole beneficiaries' or 'beneficiaries without legal personality.¹⁶

Please note that if the action will be implemented by the members, they should also participate (either as beneficiaries or as affiliated entities, otherwise their costs will NOT be eligible).

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

Countries currently negotiating association agreements — 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

-

¹⁶ See Article 197(2)(c) EU Financial Regulation 2018/1046.

(with retroactive effect, if provided in the agreement).

EU restrictive measures — Special rules apply for certain entities (e.g. entities subject to <u>EU restrictive measures</u> under Article 29 of the Treaty on the European Union (TEU) and Article 215 of the Treaty on the Functioning of the EU (TFEU) and entities covered by Commission Guidelines No <u>2013/C 205/05</u>7). 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 <u>Rules for Legal Entity Validation, LEAR Appointment and</u> 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. 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 in article 12 of the EU4Health Regulation). Projects should take into account the results of projects supported by other EU funding programmes. The synergies and complementarities must be described in the project proposals (Part B of the Application Form).

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 (call topics).

Project budget

See section 3.

Ethics

Projects must comply with highest ethical standards and applicable EU, international and national law (including Directive 2005/28 on investigational medicinal products for human use 17 and Regulation 536/2014 on clinical trials on medicinal products for human

¹⁷ Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (OJ L 91, 9.4.2005, p. 13).

use¹⁸).

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

7. Financial and operational capacity and exclusion

Financial capacity

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

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

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 <u>Rules for Legal Entity Validation</u>, <u>LEAR Appointment and</u> Financial Capacity Assessment, Financial Regulation article 196(d).

¹⁸ REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

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
- applicants' activity reports of last year
- 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 participate¹⁹:

- 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 misconduct²⁰ (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant)
- committed fraud, corruption, links to a criminal organisation, money laundering,

¹⁹ See Articles 136 and 141 of EU <u>Financial Regulation 2018/1046</u>.

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.

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 <u>Regulation No 2988/95</u> (including if done by persons having powers of representation, decision making or control, beneficial owners or persons who are essential for the award/implementation of the grant)
- created under a different jurisdiction with the intent to circumvent fiscal, social or other legal obligations in the country of origin or created another entity with this purpose (including if done by persons having powers of representation, decision making or control, beneficial owners or persons who are essential for the award/implementation of the grant).

Applicants will also be refused from participation if it turns out that²¹:

- 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*²² proposals, starting with the highest scored group, and continuing in descending order:

1) Projects focusing on a theme that is not otherwise covered by higher ranked

²¹ See Article 141 EU Financial Regulation 2018/1046.

²² Proposals with the same score.

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'.

Actions with a clear Union added value shall be considered to have exceptional utility, inter alia, where:

- (a) at least 30 % of the budget of the proposed action is allocated to Member States whose GNI per inhabitant is less than 90 % of the Union average; or
- (b) bodies from at least 14 participating Member States participate in the action, of which at least four are Member States whose GNI per inhabitant is less than 90 % of the Union 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 cost²³: Yes
- travel and subsistence unitcost²⁴: 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

²³ 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).

²⁴ 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).

declared as cost

- in-kind contributions by 3rd parties' is 'not applicable'
- kick off meeting: costs for kick-off meeting organised by the granting authority are eligible (travel costs for maximum 2 persons, return ticket to Brussels and accommodation for one night) only if the meeting takes place after the project starting date set out in the Grant Agreement; the starting date can be changed through an amendment, if needed
- project websites: communication costs for presenting the project on the participants' websites or social media accounts are eligible; 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 normally **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 quarantees

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).

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

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

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

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

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

communication and dissemination plan: Yes

additional communication and dissemination activities: Yes

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

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

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

b) submit the proposal

Access the Electronic Submission System via the Topic page in the <u>Search Funding & Tenders</u> section (or, for calls sent by invitation to submit a proposal, through the link provided in the invitation letter).

Submit your proposal in 3 parts, as follows:

- Part A includes administrative information about the applicant organisations (future coordinator, beneficiaries, affiliated entities and associated partners) and the summarised budget for the proposal. Fill it in directly online
- Part B (description of the action) covers the technical content of the proposal.
 Download the mandatory word template from the Submission System, fill it in and upload it as a PDF file
- Annexes (see section5). 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 <u>IT Helpdesk</u>. Non-IT related questions should be sent to the following email address: <u>HADEA-HP-CALLS@ec.europa.eu</u>.

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

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
- 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 <u>Portal Terms & Conditions</u>.
- **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 inkind 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

- 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 <u>AGA Annotated Model Grant Agreement</u>, 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 <u>EU Financial Regulation</u>, information about EU grants awarded is published each year on the <u>Europa website</u>.

This includes:

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

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

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