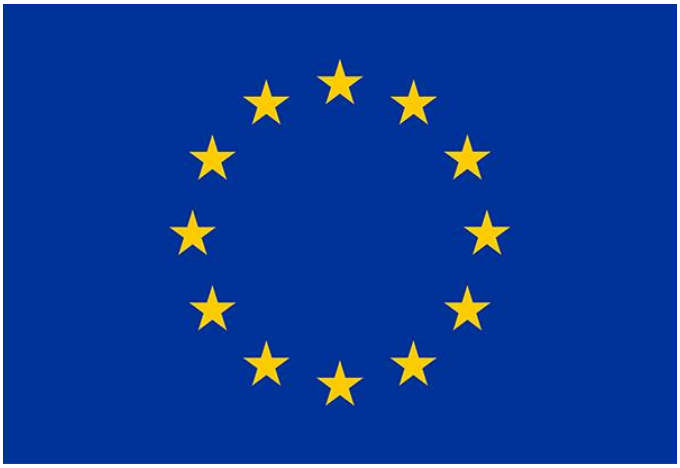

EU4Health Programme (EU4H)

Call for action grants under the Annual Work Programme 2021

EU4H-2021-PJ

Version 1.0
23 06 2021

HISTORY OF CHANGES			
Version	**Publication Date**	**Change**	**Page**
1.0	23.06.2021	▪ First version.	

EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HADEA)

HaDEA.A – Health and Food

HaDEA.A.1.1 – EU4HEALTH I

CALL FOR PROPOSALS

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Introduction

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

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

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

The call is launched in accordance with the 2021 EU4Health Work Programme[3] and will be managed by the European **Health and Digital Executive Agency, (HaDEA)** ('Agency').

The call covers the following **topics**:

- EU4H-2021-PJ-01 — Action grants on collection tasks in relation to updating the European Cancer Information System to monitor and assess cancer screening programmes (*see DP/C-g-09.2.2, 2021 EU4Health Work Programme*)
- EU4H-2021-PJ-02 — Action grants for inter-speciality cancer training programme (*see DP/C-g-10.2.1, 2021 EU4Health Work Programme*)
- EU4H-2021-PJ-03 — Action grants for a project quality and safety of radiation technology in diagnosis and treatment of cancer (*see DP/C-g-10.3.1, 2021 EU4Health Work Programme*)
- EU4H-2021-PJ-04 — Action grants for the EU Network of Youth Cancer Survivors (*see DP/C-g-11.4.1, 2021 EU4Health Work Programme*)
- EU4H-2021-PJ-05 — Action grants on substances of human origin (SoHO) - increase resilience, ensure continuity of supply and access to safe and high quality therapies, in particular in times of crisis (*see HS-g-17.2.1, 2021 EU4Health Work Programme*)

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

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

- the Call Document outlines the:

[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)4349 final of 18/06/2021 on the financing of the Programme for the Union's action in the field of health ('EU4Health Programme') and the adoption of the work programme for 2021.

  - background, objectives, scope, activities that can be funded, expected results, expected impact, mandatory specific milestones and deliverables, and the indicators (sections 1 and 2);
  - timetable, project duration and available budget (sections 3 and 4);
  - admissibility and eligibility conditions (including mandatory documents; sections 5 and 6);
  - criteria for financial and operational capacity and exclusion (section 7);
  - evaluation and award procedure (section 8);
  - award criteria (section 9);
  - legal and financial set-up of the Grant Agreements (section 10);
  - how to submit an application (section 11).

- the Online Manual outlines the:
  - procedures to register and submit proposals online via the EU Funding & Tenders Portal ('Portal');
  - recommendations for the preparation of the application;

- the AGA — Annotated Grant Agreement contains:
  - detailed annotations on all the provisions in the Grant Agreement you will have to sign in order to obtain the grant *(including cost eligibility, payment schedule, accessory obligations, etc.)*.

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

1. Background

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

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

- improve public health in the Union through disease prevention and health promotion, as well as international health initiatives and cooperation;
- protect people from serious cross-border health threats through prevention, preparedness and response to cross-border health threats; complementing national stockpiling of essential crisis-relevant products; and establishing a reserve of medical, healthcare and support staff;
- improve access to medicinal products, medical devices and crisis-relevant products by encouraging sustainable production and supply chains and innovation in the Union and efficient use of medicinal products;

- strengthen the national health systems through improved health data use and re-use, development of digital tools and services, digital transformation of healthcare; enhancing access to healthcare; developing and implementing EU health legislation and evidence-based decision making; and integrated work among Member States' health systems.

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, 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 EU4H-2021-PJ-01— Action grants on collection tasks in relation to updating the European Cancer Information System to monitor and assess cancer screening programmes

Topic EU4H-2021-PJ-01
A – Background and policy context
The European Cancer Information System (ECIS) managed by the Joint Research Centre provides the latest information on indicators that quantify cancer burden across Europe. It permits the exploration of geographical patterns and temporal trends of incidence, mortality and survival data across Europe for the major cancer entities. The survival rate for cervical, breast and colorectal cancer is a key indicator of how effective healthcare systems are in cancer care, reflecting both efficiency in early detection and the effectiveness of treatment. There is a need to further develop the ECIS to enable the monitoring and assessment of cancer screening programmes, which will require the collection of the relevant data from those entities in the Member States responsible for cancer screening. This action supports the implementation of a Europe's Beating Cancer Plan flagship initiative and links with the European Health Data Space 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 (i) of Regulation (EU) 2021/522.
B – Objectives pursued
This action supports the linking of data provided by the cancer screening programmes into ECIS with a view to allowing the permanent monitoring of the screening programmes, including the performance indicators. The action will consist in the collection of data from entities in the Member States that are responsible for collecting data on cancer screening, in order to provide this data to ECIS, and develop a piloting of the new ECIS functionality as well as a new separate section to ensure a permanent collection and monitoring of the coverage and

performance indicators of population-based cancer screening across the Union.
C – Description of the activities to be funded under this topic
1. Preparatory work through meetings (5) and workshops (5) to create a platform in which data and indicators on population-based cancer screening programmes are collected, collated and further assessed under the European Cancer Information System. 2. Actions to support the first piloting of the platform developed under point 1, including collection of available datasets related to breast, colorectal and cervical cancer screening programmes.
D – Expected results and impact
The expected result is the collection of the relevant cancer screening data from the Member States. This action aims at improving the monitoring of the implementation of cancer screening programmes across the Union, and will have an impact on the implementation of such programmes by providing the Member States with evidence-based information to strengthen their programmes.
E – Specific mandatory deliverables and/or milestones *(in addition to those listed in section C and D above)*
none
F – Specific indicators for reporting purposes
The applicants will include the following specific action-level indicators and related reporting activities in their proposals: • number of data providers (thematic coverage); • number of Member States participating; • number of data/themes collected and made available on cancer screening; • number of performance and outcome indicators made available on cancer screening; • number of data sets tested through the piloting phase; • number of access/downloads of the data. The applicants are required to include in their proposals additional specific action-level indicators which will be agreed with the HaDEA during the grant agreement preparation.

Special requirements

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.*	Participating centres/bodies/institutions are recognised as of public health relevance and able to have access to and/or collect cancer screening data. Networks in the field of public health (responsible for cancer screening); Member States' authorities; academia and education establishments; research institutes and civil society organisations (associations, foundations, NGOs and similar entities).
Applicants – consortium composition	NO
Non-eligible activities	NO
Financial support to third parties	NO
Place of implementation	NO
Ethics/Security measures:	NO

2.2 EU4H-2021-PJ-02 — Action grants for inter-speciality cancer training programme

Topic EU4H-2021-PJ-02
A – Background and policy context
An objective of Europe's Beating Cancer Plan is to build a stronger multidisciplinary cancer workforce. High-quality cancer care depends on a high-quality workforce. Patients deserve the best care possible and health professionals need support to ensure they can receive training and keep updating their skills throughout their professional lives. An 'inter-speciality cancer training programme' will be launched to help deliver a more skilled and mobile cancer workforce through cross-border training and information-sharing. This action supports the implementation of the Europe's Beating cancer Plan objective to ensure high-quality health workforce 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 this action is to update the skills of healthcare professionals and foster the development of a high-quality workforce. This action will develop an inter-speciality cancer training programme focused on clinical oncology, surgery and radiology specialities, including their nursing services, as well as on patients' quality of life and well-being, including mental, psychosocial and nutritional support, along with patient empowerment.
C – Description of the activities to be funded under this topic
Preparatory actions through meetings (5) and workshops (5) to deliver the following:

• Development of first set of curricula to be delivered for the launch of the first training in inter-speciality oncology, targeted to clinical oncology, surgery and radiology, including their respective nursing services. • Fine-tuning of needs assessments, namely estimation of the costing needed to support per centre involved and per person trained, taking into account the number of participants in the consortium. • Selection and preparation of the first cohort of trainees who will participate in the inter-speciality oncology training. • Selection and preparation of the cancer centres who will support and host the first cohort of trainees.
D – Expected results and impact
The establishment of an inter-speciality cancer training programme is expected to result in the upskilling and re-skilling of healthcare professionals in the areas of clinical oncology, surgery and radiology, and related nursing services. This action will help the Member States to improve cooperation among their cancer services, by addressing skills gaps and better equipping the health workforce with personnel trained in cancer care.
E – Specific mandatory deliverables and/or milestones *(in addition to those listed in section C and D above)*
Number of trainees and trainers
F – Specific action-level indicators for reporting purposes
The applicants will include the following specific action-level indicators and related reporting activities in their proposals: • number of training centres engaged; • number of trainers engaged; • number of supporting documents produced; • number of participants to the training courses; • satisfaction rate of participants to the training courses. The applicants are required to include in their proposals additional specific action-level indicators which will be agreed with the HaDEA during the grant agreement preparation.

Special requirements

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, research institutes, hospitals, expert networks including European Reference Networks (ERNs), Member States' authorities and established networks in the field of public health having clinical capability in cancer diagnosis, treatment and follow-up of cancer patients.
Specific eligibility criteria applicable to the consortium composition	A consortium composed of at least 15 applicant organisations established in at least 7 different eligible countries.

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.

2.3 EU4H-2021-PJ-03 — Action grants for a project on the quality and safety of radiation technology in diagnosis and treatment of cancer

Topic EU4H-2021-PJ-03
A – Background and policy context
Europe's Beating Cancer Plan will seek to ensure that people in the Union have the right to access affordable, preventive and curative healthcare of good quality, as called for under the European Pillar of Social Rights. High-quality cancer care depends on a number of factors including access to essential medicines and innovation. The large majority of current radiation technologies used in medicine address cancer diagnosis and treatment, and the quality and safety of these medical applications needs to be harmonised across the Union as it is evident that disparities exist in the applied level of such standards. In addition, the supply of radioisotopes used for cancer diagnosis and treatment is still not constant and subject to interruptions, therefore measures should be developed to ensure their sustainable supply, in particular in the long-term. This action supports the Europe's Beating Cancer Plan objective to ensure high standards in cancer care and implements the EU4Health Programme's general objective of improving and fostering health in the Union (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 enhance the quality and safety and optimise radiation technology in medicine.
C – Description of the activities to be funded under this topic
Applicants shall **target their proposal to one or more of the action strands (a, b, c)** described below and indicate that clearly in the proposal. This action will be implemented in close cooperation with the Strategic Agenda for Medical Ionising Radiation Applications of nuclear and radiation technology (SAMIRA) (SWD(2021)14 final) and the activities will be grouped as follows: **(a) Quality and safety of medical radiation applications** The action will include accompanying activities to: (1) build co-operations, support and monitor medical radiations applications, (2) develop evidence-based guidance and practical tools for quality and safety of medical ionising radiation applications, (3) build EU dose registry for patients undergoing radiological and nuclear medicine

imaging, and

(4) support to align Euratom / EU action on medical radiological diagnostic and therapeutic equipment, including acceptance and performance testing, technical standards and harmonised reporting of adverse events, align Euratom / EU action on radiopharmaceuticals, and support actions for clinical audit of radiology, nuclear medicine and radiotherapy practices.

(b) Workforce education and training

The action will include activities for the:

(1) Union-wide monitoring of workforce availability, education and training;

(2) capacity building in modern radionuclide cancer diagnosis, therapy and 'theragnostics'; and

(3) development of EU curricula and certification schemes in the quality and safety of radiology, nuclear medicine and radiotherapy.

(c) Equal access to modern medical radiation technology and interventions

The action will include:

(1) monitoring of the Union imaging and radiotherapy equipment base and the availability of modern quality and safety features;

(2) develop quality and safety criteria and optimised imaging protocols for advanced medical imaging;

(3) cover medical radiation technology, including diagnostic and therapeutic application, in national cancer plans; and

(4) improve evidence for clinical efficacy of novel cancer interventions involving ionising radiation.

Applicants have to ensure co-ordination with other SAMIRA actions, in order to avoid duplication of activities. In particular, applicants should take into account the Directorate General for Energy's calls for tenders on medical equipment and co-ordinated implementation of the legal bases for nuclear medicine and radiopharmaceuticals.

D – Expected results and impact

The action will contribute to improve the quality and safety of medical radiation applications, the standards of the workforce in the radio-nuclear medical sector through education and training, and it will facilitate a more equal access to modern medical radiation technology and interventions.

In addition, the action will help to better align Euratom and EU health actions on important issues such as safety and quality in medical and radiation applications and in radiopharmaceuticals. It will contribute to a reduction in discrepancies through a shared and harmonised approach to current radiation technology for medical applications to address cancer diagnosis and treatment.

This action will ultimately benefit cancer patients and the general population in accessing radiology and nuclear medicine services in the Member States.

E – Specific mandatory deliverables and/or milestones
(in addition to those listed in section C and D above)

Participants in the action have to regularly report on the progress of the work to the Steering Group on Quality and Safety of medical applications of nuclear and radiation technology (SGQS), to be launched under the SAMIRA action plan by the end of 2021. Indicatively, this will include providing short written updates and presentations to the

SGQS once every six months for the duration of the project.
F – Specific action-level indicators for reporting purposes
The applicants will include the following specific action-level indicators and related reporting activities in their proposals: Quality and safety of medical radiation applications • number of experts and organisations involved, by type of application; • number of manuals / guidance / relevant documents produced; • number of practical tools deployed, by type of application; • number of countries and imaging departments included in the EU dose registry. Workforce education and training • number of training materials produced; • number of training courses organised (days); • number of professionals trained, by category; • satisfaction rate of trained professionals; Equal access to modern radiation technology and interventions • number of reports produced; • number of recommendations endorsed; • number of national cancer plans covering imaging and therapeutic equipment; • number of protocols agreed/endorsed. The applicants are required to include in their proposals additional specific action-level indicators which will be agreed with the HaDEA during the grant agreement preparation.

Special requirements

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, research institutes, hospitals, expert networks including ERNs, enterprises in the field of public health, Member States' authorities and established networks in the field of public health having experience in at least one of the major fields of clinical application of ionising radiation, including radiology, nuclear medicine and radiotherapy.
Applicants – consortium composition	NO
Non-eligible activities	NO
Financial support to third parties	NO
Place of implementation	NO
Ethics/Security measures	NO

2.4 EU4H-2021-PJ-04 — Action grants for the EU Network of Youth Cancer Survivors

Topic EU4H-2021-PJ-04
A – Background and policy context
In 2020, over 15 500 children and adolescents were diagnosed with cancer, with over 2 000 young patients losing their lives to it. In fact, cancer is the principal cause of death by disease in children beyond the age of one. Up to 30% of children affected by cancer suffer severe long-term consequences. The number of childhood cancer survivors continues to grow and comprehensive care, treatment and follow-up are essential to help young patients make a good recovery and enjoy an optimal quality of life. There is a need for multidisciplinary and proactive approaches to healthy cancer survivorship, as well as for improved social networking and establishment of communication and information sharing platforms tailored specifically to young adult cancer survivors, which are well demonstrated instruments to improve the quality of life of children and young adult cancer survivors. This action supports the implementation of the Europe's Beating Cancer Plan objective to put childhood cancer under the spotlight and implements the EU4health Programme's general objective of improving and fostering in the Union (Article 3, point(a)) through the specific objectives in Article 4, points (a),(g) and (j) of Regulation (EU)2021/522.
B – Objectives pursued
The action will improve the quality of life of children and young adult cancer survivors through improved social networking and the use of a platform to improve the links amongst individuals, patients, cancer survivors, and social and health professionals active in cancer prevention and care across the Union. Building on the experiences gained by several organisations, non-governmental organisations and cancer care institutions active in childhood, adolescent, and young adult cancers, the action has the ambition of establishing the new 'EU Network of Youth Cancer Survivors' through federating the mentioned bodies to create a Union-wide platform to support the promotion of targeted actions and initiatives, covering the main areas which are of demonstrated benefit to improve the quality of life of young cancer survivors. The activities will be designed taking into account those key factors that may influence childhood cancer survivors' participation in social networking and programmes tailored to their needs, such as the resources accessed by individuals through a broad range of social connections ('social capitals of individuals'), social support, family interaction, self-efficacy and self-reported quality of life. Children, adolescents and young adult survivors will be at the core of the actions and will be the main actors in linking with their countries and/or organisation. A conference will give the possibility to show and share the results of the activities implemented and on-going across the Union, and to discuss as widely as possible the needs and challenges. The EU Network will also be open to establish international links through direct contacts with partners outside the Union or through links with international organisations. Particular attention will be given to actions limiting the disruptive impact of cancer on the education of children and young people affected by cancer. This will happen with the involvement of patients and of formal and informal carers, on a voluntary basis.
C – Description of the activities to be funded under this topic
The activities funded will be as follow:

- Preparatory activities (first 6 months of the initiative). Through meetings and parallel consultations to define / agree on structure, modus operandi, secretariat, annual programme, and other operational and organisational needs, including a costing exercise of the EU Network.
- Launch of the EU Network (February 2022) – To be organised in the European Parliament and comparable to the launch of the Europe's Beating Cancer Plan in February 2021.
- Starting the activities of the Network through ad hoc missions/webinars/workshop, with the direct involvement of EU Network delegates and 'Ambassadors'.
- First general assembly of the Network Q3 2022.
- Throughout the project, wide visibility of the actions/initiatives of the EU Network will be requested.

D – Expected results and impact

The action is expected to result in an expansion of the current support to improve the quality of life of young cancer survivors through networking, targeted actions, linking with existing organisations at Union and international level, and through highly visible periodical events to show the impact of the work done, and the future challenges.

The action will improve communication between children and adolescent cancer survivors, formal and informal carers, and civil society, and will strengthen the knowledge on how to better recognise the risk of getting cancer, and how to make a difference in the lives of young people with cancer and survivors, and allow them to learn how to become an advocate to bring key messages and knowledge on cancer survivorship to civil society.

E – Specific mandatory deliverables and/or milestones
(in addition to those listed in section C and D above)

none

F – Specific action-level indicators for reporting purposes

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

- number of events, meetings and discussions organised;
- number of documents produced for information and dissemination;
- number of initiatives supported;
- number of participants (people or entities);
- number of participants (Member State, other countries or international organisations);
- number of stakeholders/association participating per country and field.

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

Special requirements

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.*	Civil society organisations (associations, foundations, NGOs and similar entities), private entities (profit or non-profit), Member States authorities and established networks it the field of public health.
Applicants – consortium composition	NO
Non-eligible activities	NO
Financial support to third parties	NO
Place of implementation	NO
Ethics/Security measures	NO

2.5 EU4H-2021-PJ-05 — Action grants on substances of human origin (SoHO) - increase resilience, ensure continuity of supply and access to safe and high quality therapies, in particular in times of crisis

Topic EU4H-2021-PJ-05
A – Background and policy context
The COVID-19 pandemic has significantly tested the resilience of blood and transplant systems and has strongly reduced supply, availability, use and access to these therapies. There is a need to improve resilience, ensure the continuity of supply, increase access, safety and quality of therapies, in particular in times of infectious disease outbreaks. The action supports the policy priority to respond to the COVID-19 pandemic 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 (Article 3, point (c)) through the specific objectives defined in Article 4, point (c) of Regulation (EU) 2021/522.
B – Objectives pursued
This action aims to enable the medical/professional organisations and Member State authorities in SoHO subsectors to develop and exchange good practices for professionals and authorities to optimise supply and increase access to quality and safe use of critical therapies based on substances of human origin donated by fellow citizens.
C – Description of the activities to be funded under this topic
Proposed measures and actions can be targeted at local/hospital level, regional/national level and supra-national/Union level. The measures and actions developed can be implemented by professionals, in collaboration with their national authorities as appropriate, across the Union. The work will aim to identify, share, assess and refine measures and actions taken

and planned to mitigate the impact of the COVID-19 pandemic on safety, quality and accessibility of these therapies.

The specific sub-sectors that will be supported include in particular:

- blood and blood components (red blood cells, plasma);
- organs (e.g. kidneys, liver, heart);
- haematopoietic stem cells (bone marrow, cord blood);
- gametes and embryos (for reproductive medicine);
- tissues (corneas, heart valves).

D – Expected results and impact

The expected results of this action are the following:

- development and dissemination of good practices and guidance by medical/professional associations and Member States authorities in the SoHO subsectors to strengthen and make more resilient transplant, transfusion and medically assisted reproduction systems, in particular during crises;
- contribution to a more sustainable supply and increased access to essential SoHO therapies with mitigating actions to avoid disruptions (by comparison with the annual volumes monitored routinely for several SoHO subsectors).

These activities will enable professional associations and Member States authorities in the sector to ensure a more resilient supply system for sustainable access to safe SoHO. Ultimately, this action will contribute to strengthening the safety and the protection of patients receiving SoHO therapies.

E – Specific mandatory deliverables and/or milestones
(in addition to those listed in section C and D above)

- Identification of good practices and guidance for clinics and healthcare systems where existing.
- Development of good practices and guidance for clinics and healthcare systems.
- Dissemination/exchange of good practices between medical/professional association across the Union and Member States authorities.

F – Specific action-level indicators for reporting purposes

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

- number of events / meetings / exchanges organised;
- number of participants in the events (by country / sector);
- satisfaction rate of participants;
- number of best practices developed;
- number of clinics/healthcare systems with improved preparedness and response planning;
- number of transplant procedures, and other applications of Substances of Human Origin (in particular volatility in times of crisis);
- (outreach) number of stakeholders endorsing finalised good practices by: individuals / entities, Member States authorities, stakeholder associations per country/field.

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

Special requirements

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.*	Professional medical societies (with professional members from hospitals, transplant centres and blood/tissue establishments across the Union) and Member States' authorities, representing experts in one or more healthcare specialities working with substances of human origin (SoHO - solid organs, haematopoietic stem cells, tissues, gametes, blood and blood components), representing professionals in multiple EU Member States, having a strong relationship / collaboration with national/EU level authorities in the field of SoHO is needed.
Applicants – consortium composition	NO
Non-eligible activities	Investment in medical equipment or materials.
Financial support to third parties	NO
Place of implementation	NO
Ethics/Security measures	Projects must comply with: - highest ethical standards and - applicable EU, international and national law Specific national rules relating to ethics in these fields must be respected.

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

3. Available budget

The available call budget is **EUR 19 000 000**. This budget might be increased by maximum 20%.

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

Topic	Topic budget	Proposals to be awarded under this topic	Recommended project duration
EU4H-2021-PJ-O1 Action grants on collection tasks in relation to updating the European Cancer Information System to monitor and assess cancer screening programmes.	2 000 000	one or more proposals	18 months
EU4H-2021-PJ-O2 Action grants for inter-speciality cancer training programme.	5 000 000	one or more proposals	18 months
EU4H-2021-PJ-O3 Action grants for a project on the quality and safety of radiation technology in diagnosis and treatment of cancer.	3 500 000	up to 5 proposals	24 months
EU4H-2021-PJ-O4 Action grants for the EU Network of Youth Cancer Survivors.	5 000 000	one or more proposals	18 months
EU4H-2021-PJ-05 Action grants on substances of human origin (SoHO) - increase resilience, ensure continuity of supply and access to safe and high quality therapies, in	3 500 000	up to 5 proposals	30 months

particular in times of crisis.			

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:	23 June 2021
Proposal submission opening:	29 July 2021
Deadline for submission of proposals:	15 September 2021 – 17:00:00 CET (Brussels)
Evaluation:	September-November 2021
Information on evaluation results:	December 2021
GA signature:	March 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 — they are only for information).

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

- Application Form Part A — contains administrative information about the participants (future coordinator, beneficiaries and affiliated entities) and the summarised budget for the project *(to be filled in directly online)*
- Application Form Part B — contains the technical description of the project *(to be downloaded from the Portal Submission System, completed and then assembled and re-uploaded)*
- **mandatory annexes and supporting documents** *(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) **or** 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 Participant Register — before submitting the proposal — and will have to be validated by the Central Validation Service (REA Validation). For the validation, they will be requested to upload documents showing legal status and origin.

Other entities may participate in other consortium roles, such as associated partners, subcontractors, 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 persons[4].

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

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

Countries currently negotiating association agreements — Participants from countries with ongoing negotiations *(see above)* may participate in the call and can sign grants as beneficiaries eligible for funding if the negotiations are concluded before grant signature (with retroactive effect, if provided in the agreement).

EU restrictive measures — Special rules apply for certain entities *(e.g. entities subject to EU restrictive measures under Article 29 of the Treaty on the European Union (TEU) and Article 215 of the Treaty on the Functioning of the EU (TFEU)[6] and entities covered by Commission Guidelines No 2013/C 205/05[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 Rules for Legal Entity Validation, LEAR Appointment and Financial Capacity Assessment*.

Consortium composition

Proposals must be submitted by a consortium of at least 3 applicants (beneficiaries; not affiliated entities), which complies with the following conditions:

4 See Article 197(2)(c) EU Financial Regulation 2018/1046.
5 For the definitions, see Articles 187(2) and 197(2)(c) EU Financial Regulation 2018/1046.
6 Please note that the EU Official Journal contains the official list and, in case of conflict, its content prevails over that of the EU Sanctions Map.
7 Commission guidelines No 2013/C 205/05 on the eligibility of Israeli entities and their activities in the territories occupied by Israel since June 1967 for grants, prizes and financial instruments funded by the EU from 2014 onwards (OJEU C 205 of 19.07.2013, pp. 9-11).

– 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).

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[8] and Regulation 536/2014 on clinical trials on medicinal products for human use[9]).

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 Participant Register during grant preparation *(e.g. profit and loss account and balance sheet, business plan, audit report produced by an*

[8] 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).

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

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)
- prefinancing paid in instalments
- (one or more) prefinancing guarantees (see below, section 10)

or

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

 For more information, *see Rules for Legal Entity Validation, LEAR Appointment and Financial Capacity Assessment, Financial Regulation article 196(d)*.

Operational capacity

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

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

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

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

- general profiles (qualifications and experiences) of the staff responsible for managing and implementing the project
- description of the consortium participants
- 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 participate[10]:

- bankruptcy, winding up, affairs administered by the courts, arrangement with creditors, suspended business activities or other similar procedures (including procedures for persons with unlimited liability for the applicant's debts)
- in breach of social security or tax obligations (including if done by persons with unlimited liability for the applicant's debts)
- guilty of grave professional misconduct[11] (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant)
- committed fraud, corruption, links to a criminal organisation, money laundering, terrorism-related crimes (including terrorism financing), child labour or human trafficking (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant)
- shown significant deficiencies in complying with main obligations under an EU procurement contract, grant agreement, prize, expert contract, or similar (including if done by persons having powers of representation, decision making or control, beneficial owners or persons who are essential for the award/implementation of the grant)
- guilty of irregularities within the meaning of Article 1(2) of Regulation No 2988/95 (including if done by persons having powers of representation, decision making or control, beneficial owners or persons who are essential for the award/implementation of the grant)
- created under a different jurisdiction with the intent to circumvent fiscal, social or other legal obligations in the country of origin or created another entity with this purpose (including if done by persons having powers of representation, decision making or control, beneficial owners or persons who are essential for the award/implementation of the grant).

Applicants will also be refused from participation if it turns out that[12]:

- 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).

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

[11] 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.

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

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*[13] proposals, starting with the highest scored group, and continuing in descending order:

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

2) The *ex aequo* proposals within the same topic will be prioritised according to the scores they have been awarded for the award criterion 'Relevance'. When these scores are equal, priority will be based on their scores for the criterion 'Impact'. When these scores are equal, priority will be based on their scores for the criterion 'Quality'.

3) If this does not allow to determine the priority, a further prioritisation can be done by considering the overall project portfolio and the creation of positive synergies 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

[13] Proposals with the same score.

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.

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

Overall threshold: 70 points.

Proposals that pass the individual thresholds AND the overall threshold will be considered for funding — within the limits of the available 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 cost[14]: Yes
- travel and subsistence unit cost[15]: 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)

[14] 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).

[15] 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).

- VAT: non-deductible VAT is eligible (but please note that since 2013 VAT paid by beneficiaries that are public bodies acting as public authority is NOT eligible)
- other:
  - in-kind contributions for free are allowed, but cost-neutral, i.e. they cannot be declared as cost
  - 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 **prefinancing** to start working on the project (float of normally **30%** of the maximum grant amount; exceptionally less or no prefinancing). The prefinancing will be paid 30 days from entry into force/10 days before starting date/financial guarantee (if required) — whichever is the latest.

There will be one or more **interim payments** (with detailed cost reporting).

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

All payments will be made to the coordinator.

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

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

Prefinancing guarantees

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

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

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

Prefinancing guarantees are formally NOT linked to individual consortium members, which means that you are free to organise how to provide the guarantee amount *(by*

one or several beneficiaries, for the overall amount or several guarantees for partial amounts, by the beneficiary concerned or by another beneficiary, etc.). It is however important that the requested amount is covered and that the guarantee(s) are sent to us in time to make the prefinancing (scanned copy via Portal AND original by post).

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

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

Certificates

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

Liability regime for recoveries

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

For beneficiaries, it is one of the following:

- limited joint and several liability with individual ceilings — *each beneficiary up* to their maximum grant amount
- unconditional joint and several liability — *each beneficiary up to the maximum grant amount for the action*

or

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

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

Provisions concerning the project implementation

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

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

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

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

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

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

– specific rules for blending operations: No

Other specificities

n/a

Non-compliance and breach of contract

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

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

11. How to submit an application

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

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

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

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

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

b) **submit the proposal**

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

Submit your proposal in 3 parts, as follows:

- Part A includes administrative information about the applicant organisations (future coordinator, beneficiaries, affiliated entities and associated partners) and the summarised budget for the proposal. Fill it in directly online
- Part B (description of the action) covers the technical content of the proposal. Download the mandatory word template from the Submission System, fill it in and upload it as a PDF file
- Annexes (*see section 5*). Upload them as PDF file (single or multiple depending on the slots). Excel upload is sometimes possible, depending on the file type.

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

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

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

Once the proposal is submitted, you will receive a **confirmation e-mail** (with date and time of your application). If you do not receive this confirmation e-mail, it means

your proposal has NOT been submitted. If you believe this is due to a fault in the Submission System, you should immediately file a complaint via the IT Helpdesk webform, explaining the circumstances and attaching a copy of the proposal (and, if possible, screenshots to show what happened).

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

12. Help

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

- Online Manual
- FAQs on the Topic page (for call-specific questions in open calls)
- Portal FAQ (for general questions).

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

Contact

For individual questions on the Portal Submission System, please contact the IT Helpdesk.

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

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

13. Important

IMPORTANT

- **Don't wait until the end —** Complete your application sufficiently in advance of the deadline to avoid any last minute **technical problems**. Problems due to last minute submissions *(e.g. congestion, etc)* will be entirely at your risk. Call deadlines can NOT be extended.
- **Consult** the Portal Topic page regularly. We will use it to publish updates and additional information on the call (call and topic updates).
- **Funding & Tenders Portal Electronic Exchange System —** By submitting the application, all participants **accept** to use the electronic exchange system in accordance with the Portal Terms & Conditions.
- **Registration —** Before submitting the application, all beneficiaries, affiliated entities and associated partners must be registered in the Participant Register. The participant identification code (PIC) (one per participant) is mandatory for the Application Form.
- **Consortium roles—** When setting up your consortium, you should think of organisations that help you reach objectives and solve problems.

  The roles should be attributed according to the level of participation in the project. Main participants should participate as **beneficiaries** or **affiliated entities**; other entities can participate as associated partners, subcontractors, third parties giving in-kind contributions. **Associated partners** and third parties giving in-kind contributions should bear their own costs (they will not become formal recipients of EU funding). **Subcontracting** should normally constitute a limited part and must be performed by third parties (not by one of the beneficiaries/affiliated entities). Subcontracting going beyond 30% of the total eligible costs must be justified in the application.
- **Coordinator —** In multi-beneficiary grants, the beneficiaries participate as consortium (group of beneficiaries). They will have to choose a coordinator, who will take care of the project management and coordination and will represent the consortium towards the granting authority. In mono-beneficiary grants, the single beneficiary will automatically be coordinator.
- **Affiliated entities** — Applicants may participate with affiliated entities (i.e. entities linked to a beneficiary which participate in the action with similar rights and obligations as the beneficiaries, but do not sign the grant and therefore do not become beneficiaries themselves). They will get a part of the grant money and must therefore comply with all the call conditions and be validated (just like beneficiaries); but they do not count towards the minimum eligibility criteria for consortium composition (if any).
- **Associated partners** — Applicants may participate with associated partners (i.e. partner organisations which participate in the action but without the right to get grant money). They participate without funding and therefore do not need to be validated.
- **Consortium agreement** — For practical and legal reasons it is recommended to set up internal arrangements that allow you to deal with exceptional or unforeseen circumstances (in all cases, even if not mandatory under the Grant Agreement). The consortium agreement also gives you the possibility to redistribute the grant money according to your own consortium-internal principles and parameters (for instance, one beneficiary can reattribute its grant money to another beneficiary). The consortium agreement thus allows you to customise the EU grant to the needs inside your consortium and can also help to protect you in case of disputes.

- **Balanced project budget —** Grant applications must ensure a balanced project budget and sufficient other resources to implement the project successfully *(e.g. own contributions, income generated by the action, financial contributions from third parties, etc.)*. You may be requested to lower your estimated costs, if they are ineligible (including excessive).

- **No-profit rule —** Grants may NOT give a profit (i.e. surplus of revenues + EU grant over costs). This will be checked by us at the end of the project.

- **No double funding —** There is a strict prohibition of double funding from the EU budget (except under EU Synergies actions). Outside such Synergies actions, any given action may receive only ONE grant from the EU budget and cost items may under NO circumstances declared to two different EU actions.

- **Completed/ongoing projects —** Proposals for projects that have already been completed will be rejected; proposals for projects that have already started will be assessed on a case-by-case basis (in this case, no costs can be reimbursed for activities that took place before the project starting date/proposal submission).

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

- **Multiple proposals —** Applicants may submit more than one proposal for *different* projects under the same call (and be awarded a funding for them).

  Organisations may participate in several proposals.

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

- **Resubmission —** Proposals may be changed and re-submitted until the deadline for submission.

- **Rejection —** By submitting the application, all applicants accept the call conditions set out in this this Call Document (and the documents it refers to). Proposals that do not comply with all the call conditions will be **rejected**. This applies also to applicants: All applicants need to fulfil the criteria; if any one of them doesn't, they must be replaced or the entire proposal will be rejected.

- **Cancellation —** There may be circumstances which may require the cancellation of the call. In this case, you will be informed via a call or topic update. Please note that cancellations are without entitlement to compensation.

- **Language —** You can submit your proposal in any official EU language (project abstract/summary should however always be in English). For reasons of efficiency, we strongly advise you to use English for the entire application. If you need the call documentation in another official EU language, please submit a request within 10 days after call publication (for the contact information, *see section 12*).

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

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

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

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