



# Union Civil Protection Mechanism (UCPM)

# Call for proposals – Invitation to submit a proposal

rescEU Stockpiling of medical countermeasures and/or personal protective equipment, aimed at combatting serious cross-border threats to health

(UCPM-2021-rescEU-Capacities-IBA)

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# **EUROPEAN COMMISSION**

Directorate-General for European Civil Protection and Humanitarian Aid Operations (ECHO)

ECHO.A – Emergency Management and rescEU ECHO.A.02 – Capacities and Operational Support

# **CALL FOR PROPOSALS**

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#### 0. Introduction

This is an invitation to submit proposals for EU **action grants** in the field of rescEU medical capacities under the **Union Civil Protection Mechanism**.

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

- Regulation 2018/1046 (<u>EU Financial Regulation</u>)
- the basic act (UCPM Decision <u>1313/2013/EU</u><sup>1</sup>)
- Implementing Decision (EU) 2019/570.

The invitation is launched in accordance with the <u>2021 Work Programme</u><sup>2</sup> and will be managed by the European Commission, Directorate-General for European Civil Protection and Humanitarian Aid Operations (DG ECHO).

The call covers the following **topics**:

 UCPM-2021-rescEU-Capacities — rescEU Stockpiling of medical countermeasures and/or personal protective equipment, aimed at combatting serious cross-border threats to health

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

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

- the <u>Call Document</u> outlines the:
  - background, objectives, scope, activities that can be funded and the expected results (sections 1 and 2)
  - available budget and timetable (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')

Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism (OJ L 347, 20.12.2013, p. 924).

Commission Implementing Decision C(2021)4759 final of 1 July 2021 amending Implementing Decision C(2021)935 on the financing of the Union Civil Protection Mechanism and adopting a multi-annual work programme for years 2021-2023.

- 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.).

#### 1. Background

The Union Civil Protection Mechanism ('the Union Mechanism') governed by Decision No 1313/2013/EU³ as amended by Decision 2019/420/EU⁴ (hereafter "Decision No 1313/2013/EU″), strengthens cooperation between the Union and the Member States and facilitates coordination in the field of civil protection in order to improve the Union's response to natural and man-made disasters.

Decision No 1313/2013/EU defines the legal framework of rescEU. rescEU aims to provide assistance in overwhelming situations where overall existing capacities at national level and those committed by Member States to the European Civil Protection Pool are not able to ensure an effective response.

Implementing Decision (EU) 2019/1310<sup>5</sup> specifies the rules applicable to rescEU capacities (criteria for deployment, demobilisation and disengagement).

In the beginning of 2020 the COVID-19 pandemic made evident the gaps in health preparedness and showed that medical capacities available via the Union Mechanism were insufficient to respond to the needs of countries requesting assistance. As a consequence, the initial scope of the foreseen rescEU medical stockpiling capacity was enlarged to cover all serious cross-border health threats as defined as defined in Decision No  $1082/2013/EU^6$ 

Implementing Decision (EU) 2019/570<sup>7</sup>, as amended by Implementing Decision (EU) 2020/414, includes medical stockpiling capacities under rescEU and lays down the relevant quality requirements for stockpiling capacities.

#### 2. Objectives — Expected outcomes — Capacity to be developed

UCPM-2021-rescEU-Capacities — rescEU Stockpiling of medical countermeasures and/or personal protective equipment, aimed at combatting serious cross-border threats to health

# <u>Objectives</u>

The objective of this call for proposals is to develop and maintain a rescEU stockpile of medical countermeasures and/or personal protective equipment aimed at combatting

Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism, OJ L 347, 20.12.2013, p. 924–947.

<sup>4</sup> https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32019D0420

Commission Implementing Decision (EU) 2019/1310 of 31 July 2019 laying down rules on the operation of the European Civil Protection Pool and rescEU (notified under document C(2019) 5614), OJ L 204, 2.8.2019, p. 94–99

<sup>&</sup>lt;sup>6</sup> https://eur-lex<u>.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02013D1082-20131105</u>

Commission Implementing Decision (EU) 2020/414 of 19 March 2020 amending Implementing Decision (EU) 2019/570 as regards medical stockpiling rescEU capacities

cross-border health threats.

#### Expected outcomes

The expected outcome is the availability of response capacities, namely "last resort" emergency stockpiles of medical countermeasures and/or personal protective equipment. These capacities may be deployed in case the requests for assistance cannot be covered by bilateral offers, voluntary offers of items pre-committed to the European Civil Protection Pool.

#### Capacity to be developed

Stockpiling capacities to be developed need to be in line with the technical specifications laid down in Section 6 of the Annex of Decision (EU) 2019/570<sup>8</sup>, as amended by Implementing Decision (EU) 2020/414.

The scope of the grant should include the development of the capacity as well as its maintenance costs until 2026 and all activities needed to ensure effective deployment (e.g. registration in CECIS, preparation of SOPs for deployment).

The rescEU stockpiles should:

- be able to respond to a wide range of scenarios with a priority for cross-border spread of infectious disease scenarios
- be able to respond to a variety of agents with some priority for air-spread infectious agents, contact HCID, and/or biological and or non-biological toxin
- have a preferred number between 5 and 10 rescEU medical stockpiles
- take into account geographical distribution
- be composed of a diversity of different items.

The stockpile to be developed may cover the following items, for the purpose of preparedness and response to cross-border health threats:

- 1. Intensive care medical equipment: dialysis and connected equipment, portable suction machines, monitors, oxygen concentrators, infusion pumps, ultrasound machines, air disinfectants for infectious agents and/or
- 2. Vaccines: Ebola vaccine, Rabies vaccine, Smallpox and/ or
- 3. Therapeutics: Ebola therapeutics and other hazard specific drugs for highly infectious diseases, Botulinum, Diphtheria and other antitoxins, Naloxon, Rabies Immunoglobulin and/or
- 4. Laboratory supplies: mobile PCR test equipment, laboratory equipment and consumables, antigen tests, vaccine transport equipment- boxes, pods and/or
- 5. Personal protective equipment: reusable protective mask, full body protection, protection hoods with blower, patient isolation transport facilities (e.g. epishuttle), goggles. The proposal should take into account the number and type of items in stock in already existing rescEU stockpiling capacities.

A detailed list of technical specification is included in Annex 1 at the end of the

Commission Implementing Decision (EU) 2020/414 of 19 March 2020 amending Implementing Decision (EU) 2019/570 as regards medical stockpiling rescEU capacities

present call document.

#### 3. Available budget

The available call budget will come from Next Generation EU and will be indicatively **EUR 150 000 000**.

We reserve the right not to award all available funds depending on the proposals received and the results of the evaluation.

#### 4. Timetable and deadlines

Timetable and deadlines		
Call opening:	19 July 2021	
Deadline for submission:	30 September 2021 – 17:00:00 CET (Brussels)	
Evaluation (tentative):	October-November 2021	
Information on evaluation results (tentative):	October -November 2021	
GA signature (tentative):	November-December 2021	

#### 5. Admissibility and documents

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

Proposals must be submitted **electronically** via the Funding & Tenders Portal Electronic Submission System (accessible via the link in the invitation letter). 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 (mandatory word template to be downloaded from the Portal Submission System, completed and then assembled and re-uploaded as PDF).

- Mandatory annexes and supporting documents (to be uploaded):
  - Detailed budget table

(mandatory excel template available in the Submission System)

- Activity reports of last year: not applicable to public authorities, mandatory for private entities
- Letter of mandate from the competent national civil protection authority of each country that will benefit from the action (except for participants which themselves are the national authority)
- Checklist on compliance with the quality requirements of Decision (EU)2019/570
   (applicants shall copy the list in Annex 2 to the present call document and attach it at the end of the application form Part B before assembling and uploading as one PDF file).
- Payment schedule
   (see template in Annex 3 to this call document)

The Description of Action and the annexes must be drafted in one of the EU official languages. However, in order to facilitate assessment by evaluators, applicants are encouraged to submit their application in English.

Please note that the amounts entered into the summarised budget table (filled in directly online) must correspond to the amounts calculated in the detailed budget table. In case of discrepancies, the amounts in the online summarised budget table will prevail.

At proposal submission, you will have to confirm that you have the **mandate to act** for all applicants. Moreover you will have to confirm that the information in the application is correct and complete and that the participants comply with the conditions for receiving EU funding (especially eligibility, financial and operational capacity, exclusion, etc.). Before signing the grant, each beneficiary and affiliated entity will have to confirm this again by signing a declaration of honour (DoH). Proposals without full support will be rejected.

Your application must be **readable**, **accessible and printable**.

Proposals are limited to maximum **70 pages** (Part B). Evaluators will not consider any additional pages.

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

For more information about the submission process (including IT aspects), consult the <a href="Online Manual">Online Manual</a>.

#### 6. Eligibility

#### Eligible participants (eligible countries)

Proposals may be submitted by Member States' competent authorities or other entities authorised by the Member State to develop rescEU capacities and to request and receive financial support from the Commission on behalf of that Member State.

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

be legal entities (public or private bodies)

- be established in one of the eligible countries, i.e.:
  - EU Member States (including overseas countries and territories (OCTs))
  - UCPM Participating States: Iceland, Montenegro, North Macedonia, Norway, Serbia and Turkey (<u>list of participating countries</u>).

All participants and affiliated entities must register in the <u>Participant Register</u> — before submitting the proposal. The participants and affiliated entities proposed to be awarded a grant will have to be validated by the Central Validation Service (conducted by Research Executive Agency) before the signature of the grant agreement. For the validation, they will be requested to upload to upload in the Participant Register documents showing legal status and origin.

Other entities may participate in other consortium roles, such as associated partners, subcontractors, third parties giving in-kind contributions, etc. (see section 13).

#### Specific cases

Natural persons are NOT eligible.

International organisations are not eligible.

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<sup>9</sup>.

EU bodies 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'<sup>10</sup>. 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).

Countries currently negotiating association agreements — Beneficiaries from countries with ongoing negotiations may participate in the call and can sign grants if the negotiations are concluded before grant signature (with retroactive effect, if provided in the agreement).

EU restrictive measures — Special rules apply for certain entities (e.g. entities subject to <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)<sup>11</sup> and entities covered by Commission Guidelines No <u>2013/C 205/05</u><sup>12</sup>). 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 Financial Capacity Assessment</u>.

<sup>10</sup> For the definitions, see Articles 187(2) and 197(2)(c) EU Financial Regulation 2018/1046.

<sup>&</sup>lt;sup>9</sup> See Article 197(2)(c) EU Financial Regulation 2018/1046.

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.

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).

#### Consortium composition

Applications by single applicants are allowed (single beneficiaries; affiliated entities and other participants are allowed, if needed).

#### Eligible capacities/assets

RescEU capacities shall meet relevant quality requirements specified in the Annex of the Implementing Decision (EU) 2019/570.

#### Eligible activities

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

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

#### Ineligible activities

The following activities are not considered as eligible for funding under this invitation, as they will be funded under other grants:

- Activities linked to the deployment of items under rescEU
- Maintenance after deployment activities
- Replenishment after deployment activities.

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).

#### **Security**

Projects involving EU classified information must undergo security scrutiny to authorise funding and may be made subject to specific security rules (detailed in a security aspects letter (SAL) which is annexed to the Grant Agreement).

These rules (governed by Decision  $2015/444^{13}$  and its implementing rules and/or national rules) provide for instance that:

- projects involving information classified TRES SECRET UE/EU TOP SECRET (or equivalent) can NOT be funded
- classified information must be marked in accordance with the applicable security instructions in the SAL
- information with classification levels CONFIDENTIEL UE/EU CONFIDENTIAL or above (and RESTREINT UE/ EU RESTRICTED, if required by national rules) may be:
  - created or accessed only on premises with facility security clearing (FSC) from the competent national security authority (NSA), in

See Commission Decision 2015/544/EU, Euratom of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

accordance with the national rules

- handled only in a secured area accredited by the competent NSA
- accessed and handled only by persons with valid personnel security clearance (PSC) and a need-to-know
- at the end of the grant, the classified information must either be returned or continue to be protected in accordance with the applicable rules
- action tasks involving EU classified information (EUCI) may be subcontracted only with prior written approval from the granting authority and only to entities established in an EU Member State or in a non-EU country with a security of information agreement with the EU (or an administrative arrangement with the Commission)
- disclosure of EUCI to third parties is subject to prior written approval from the granting authority.

Please note that, depending on the type of activity, facility security clearing may have to be provided before grant signature. The granting authority will assess the need for clearing in each case and will establish their delivery date during grant preparation. Please note that in no circumstances can we sign any grant agreement until at least one of the beneficiaries in a consortium has facility security clearing.

Further security recommendations may be added to the Grant Agreement in the form of security deliverables (e.g. create security advisory group, limit level of detail, use fake scenario, exclude use of classified information, etc.).

Beneficiaries must ensure that their projects are not subject to national/third-country security requirements that could affect implementation or put into question the award of the grant (e.g. technology restrictions, national security classification, etc.). The granting authority must be notified immediately of any potential security issues.

#### 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, LEAR Appointment and</u> Financial Capacity Assessment.

#### Operational capacity

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

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

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

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

- the description of the applicants provided in Part B Project Technical Description
- applicants' activity reports of last year
- the list of previous international deployments of the capacity provided in Part B Project Technical Description
- 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<sup>14</sup>:

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

- 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<sup>15</sup> (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 if it turns out that 16:

- 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** 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 against the operational capacity and award criteria and then ranked according to their scores (see sections 7 and 9).

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.

See Article 141 EU Financial Regulation 2018/1046.

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 agreement.

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 <u>Funding & Tenders Portal Terms and Conditions</u>). Please also be aware that for complaints submitted electronically, there may be character limitations.

#### 9. Award criteria

The award criteria facilitate the evaluation of proposals in relation to the set objectives and priorities. They enable the selection of proposals which the Commission can be confident will comply with its objectives and priorities.

The **award criteria** for this call are as follows:

#### – Relevance (maximum 35 points):

#### Criteria

Relevance of the type of items and amounts included in the stockpile to be developed and its contribution to the general rescEU objectives, taking into account the quality requirements laid down in the Annex of Implementing Decision (EU) 2019/570 and the requirements determined in the Task Team meetings (items not yet in stock, items of higher importance, etc.)

Technical quality of the items proposed (high quality, innovative solutions)

Logistics (warehousing, storage conditions, ease of transport; set-up time and weight; modularity of the capacity and ease of deployment of individual components; closeness to major roads and/or airports)

Interoperability with relevant existing EU capacities and compliance with applicable international standards.

Comparative relevance (why funding this capacity brings a higher value to the EU than funding another solution e.g. versatility)

### Quality (maximum 35 points):

#### Criteria

Concept and methodology for implementing the project (quality assurance, project management, project schedule, risk management, monitoring and evaluation)

Sustainable management of stocked medical countermeasures and personal protective equipment throughout the duration of the action and strategies to manage aspects such as perishability (e.g. a first in, first out system; use of perishable products by hospitals or other health care institutions, etc).

Procedures to ensure appropriate regular maintenance of stocked medical countermeasures and personal protective equipment throughout the duration of the action

Existing comparable in-country capacities and experience

Cost effectiveness (sufficient/appropriate budget for proper implementation; best value for money)

Is the proposal implementable within the proposed timeframe? The action needs to be implemented by 31 December 2026. No extension can be granted.

Risk evaluation (based on risk assessment by applicant and risk analysis by evaluators)

#### - Impact (maximum 30 points):

#### Criteria

Effective deployability (time for departure, location and access to the stockpiles, mitigating measures foreseen in case of disrupted international transport for the deployment)

Policies, strategies, and procedures to face low offer of medical countermeasures and personal protective equipment, and to ensure the security of supplies.

Environmental impact- "greening" measurers in the development and maintenance of the capacity (avoiding over packaging, biodegradable packing, lower carbon footprint, recycling, etc)

Ability to deploy and respond in a range of different geographic, industrial, societal settings adequately, in an inclusive and gender-balanced way (different sizes of masks, ventilators adequate for adults and children, etc)

Communication/ dissemination and visibility

Maximum score: 100 points.

Individual thresholds: 60% per criterion.

Overall threshold: 60 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.

The applications will be **ranked** according to their total score. Should two or more proposals obtain equal total scores, they will be ranked according their score for criterion "Relevance", then if a tie remains, according to their score for criterion "Quality".

In addition to the above-mentioned award criteria, when awarding the projects, the Commission reserves the right to take into account the geographical repartition of the capacities to ensure an optimal coverage of the EU. In case of competing proposals

within the same geographical area, proposals with the same overall score will be ranked according to their score for criterion "Relevance".

#### 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 <a href="Portal Reference Documents">Portal Reference Documents</a>.

#### 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: the implementation of the action cannot go beyond 30 September 2026 and the final payment must be made before 31 December 2026. The duration may not be extended.

#### 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 are mandatory for all projects:

- Annual progress reports and a risk management plan
- SOPs for deployment, to be provided as soon as the capacity is developed
- Registration in CECIS

#### 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): No minimum or maximum limit. 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 (100%).

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, non-compliance with the visibility 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
- E. Indirect costs: not eligible

#### Specific cost eligibility conditions for this call:

The eligible categories of costs linked to the development and maintenance of the rescEU capacity are exhaustively listed in Annex 1A of the Decision 1313/2013/EU:

- 1. Equipment costs
- 2. Maintenance costs, including repair costs
- 3. Insurance costs
- 4. Training costs
- 5. Warehousing costs
- 6. Registration and certification costs
- 7. Cost of consumables
- 8. Cost of personnel required to ensure the availability and deployability of rescEU capacities.

In case of deployment of the capacities under rescEU, the costs directly linked to deployment, such as the cost of the personnel deployed or travel and subsistence during deployment, will be covered by a separate grant agreement and therefore cannot be declared under this grant agreement so as to avoid double funding.

#### Personnel costs:

- SME owner/natural person unit cost<sup>17</sup>: Yes
- volunteers unit cost<sup>18</sup>. No

Commission <u>Decision</u> of 20 October 2020 authorising the use of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary for the work carried out by themselves under an action or work programme (C(2020)7715).

Travel and subsistence unit cost 19: Yes if linked to one of the categories listed in Annex IA of Decision 1313/2013/EU

Equipment costs: full cost for the items composing the capacity as described in section 2 + depreciation for support items such as warehouses

Costs for financial support to third parties are not allowed.

Indirect costs are not eligible (0% of the eligible direct costs (categories A-D).

VAT is NOT eligible.

In-kind contributions for free are allowed, but cost-neutral, i.e. they cannot be declared as cost.

Visibility, communication: costs linked to the visibility of the project are eligible (stickers, newsletters, etc.); costs for presenting the project on the participants' websites or social media accounts are eligible but 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 **first pre-financing** to start working on the project (exceptionally no pre-financing). The pre-financing will be paid 30 days from entry into force of the grant agreement (if required) — whichever is the latest.

There will be one or more **additional pre-financing payments** linked to a pre-financing report.

The sum of all pre-financing payments will not exceed 80% of the maximum amount of the grant.

The pre-financing amounts will be calculated as a percentage of the maximum grant amount and the base of the financing plan to be provided with the application (see Annex 3 of this call document).

**Payment of the balance**: At the end of the project, the Commission will calculate the final grant amount on the base of the final report submitted by the Coordinator. If the total of earlier payments is higher than the final grant amount, the Commission will ask the 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.

Commission <u>Decision</u> of 10 April 2019 authorising the use of unit costs for declaring personnel costs for the work carried out by volunteers under an action or a work programme (C(2019)2646).

Commission <u>Decision</u> of 12 January 2021 authorising the use of unit costs for travel, accommodation and subsistence costs under an action or work programme under the 2021-2027 multi-annual financial framework (C(2021)35).

#### 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*).

A CFS must be provided for each beneficiary and affiliated entity when the requested EU contribution at interim or final payment is EUR 325 000 or more.

#### 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

Security rules: see Model Grant Agreement (art 13 and Annex 5)

Intellectual property rights (IPR) rules: see Model Grant Agreement (art 16 and

#### Annex 5):

rights of use on results: Yes

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

- additional communication and dissemination activities: Yes
- limited communication and visibility to protect persons involved: No
- visibility in field operations outside the EU: Yes

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

- zero tolerance: Yes
- transfer of assets at the end of the action: not applicable to this invitation
- EU restrictive measures: Yes

#### 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 <u>AGA — Annotated Grant Agreement</u>.

#### 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 EU Login 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 through the following link:

https://ec.europa.eu/research/participants/submission/manage/screen/submission/cr eate-draft/21408?topic=UCPM-2021-rescEU-Capacities-IBA

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. Please copy the checklist in Annex 2 of the present call document and attach it at the end of the application form Part B before assembling and uploading as one 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 **project acronym** should follow the structure: rescEU-MEDSTOCK-[country].

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 FAOs 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
- 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

Non-IT related questions should be sent to the following email address: ECHO-RESCEU@ec.europa.eu.



# Please:

- send your questions at the latest 7 days before the submission deadline (see section 4)

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

#### 13. Important

# 1

#### 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.
- **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 <u>Participant Register</u>. 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 <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
- o 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  $\frac{\text{Funding \& Tenders Portal Privacy Statement}}{\text{Tenders Portal Privacy Statement}}$ .

# Annex 1: Application compendium (Description of the capacity)

The following information refers to key elements to include in the application form in the Funding & Tenders Portal, as part of the proposal for a rescEU stockpiling capacity.

The applicant should describe the specifications of the capacity components based on the quality requirements set out in the Annex of Implementing Decision (EU) 2019/570 and the requirements presented in section 2 of the present call document. Further, the applicant should provide information based on all award criteria presented in section 9 of the present call document.

The applicant should specify whether the proposal refers to:

- Personal protective equipment: reusable protective mask, full body protection, protection hoods with blower, patient isolation transport facilities (e.g. epishuttle), goggles and/or
- Intensive care medical equipment: dialysis and connected equipment, portable suction machines, monitors, oxygen concentrators, infusion pumps, ultrasound machines, air disinfectants for infectious agents and/or
- Vaccines: Ebola vaccine, Rabies vaccine, Smallpox and/ or
- Therapeutics: Ebola therapeutics and other hazard specific drugs for highly infectious diseases, Botulinum, Diphtheria and other antitoxins, Naloxon, Rabies Immunoglobulin and/or
- Laboratory supplies: mobile PCR test equipment, laboratory equipment and consumables, antigen tests, vaccine transport equipment-boxes, pods.

#### Technical specifications (Ref.1.2 of the Application form - Part B)

The applicant should report the following technical specifications per capacity component and/or capacity group:

- Name and category of product, number of items, reusable/ disposable (if relevant), size, spare parts and accessories included
- For each component: shelf-life, expiry date; versatility; storage requirements including temperature; disposal requirements.
- Standards followed, regulatory status
- Physical/ virtual stockpile, special transport requirements

# Logistics (Ref. 1.2 of the Application form – Part B)

The applicant should report the following technical specifications per capacity component and/or capacity group:

- Warehouse (storage conditions, ease of transport; location and access to major roads and/or airports)
- Set-up time and weight; time for departure, modularity of the capacity and ease of deployment of individual components;

#### Interoperability (Ref.3.2 of the Application form - Part B)

The applicant should:

• Explain how appropriate quality and technical standards will be ensured and whether specific standard operating procedures (SOPs) will be used

#### Strategy

The applicant should:

- Describe how an effective deployability of the capacity will be ensured (SOPs, time for departure, location and access to the capacity, mitigating measures foreseen in case of disrupted international transport for the deployment)
- List identified risks and risk management strategies and provisions to monitor, mitigate, transfer or eliminate the risks (policies, strategies, and procedures to face low offer of medical countermeasures and personal protective equipment, and to ensure the security of supplies).
- Describe their ability to deploy and respond in a range of different geographic, industrial, societal settings adequately, in an inclusive and gender-balanced way (gender balanced team)
- Describe procedures to ensure sustainable management of stocked medical countermeasures and personal protective equipment throughout the duration of the action and strategies to manage aspects such as perishability (e.g. a first in, first out system; use of perishable products by hospitals or other health care institutions, etc).
- Describe procedures to ensure appropriate regular maintenance of stocked medical countermeasures and personal protective equipment throughout the duration of the action
- List existing comparable in-country capacities and experience
- Describe the actions that will minimalize the negative environmental impact connected to the development of the capacity - "greening" measurers in the development and maintenance of the capacity (avoiding over packaging, biodegradable packing, lower carbon footprint, recycling, etc)
- Describe which actions are going to be put in place to ensure communication, dissemination and visibility of funding.

#### Methodology

The applicant should explain:

- Project and risk management approach and governance
- Methodology for implementation
- Budget allocations.

#### **Innovation and versatility**

If applicable, the applicant should explain the innovative nature or uniqueness of the solutions proposed including correspondent risks and added value of such innovations, as well as the versatility of the product.

# Annex 2: Compliance with minimum requirements set out in Implementing Decision (EU) 2019/570

	•	confirms that the following conditions are met per capacity component ty group proposed in this application:	
	Personal protective equipment, medical devices and laboratory supplies be relevant CE- markings and comply with:		
	0	Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on individual protective equipment, or Regulation (EU) 2017/45 on medical devices, or Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 or Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices or other relevant EU legislation	
	Vaccin	es and therapeutics fulfil one of the following requirements:	
	0	Marketing authorisation from EMA; A positive recommendation for compassionate or emergency use from EMA or a national regulatory agency of a Member State; A positive recommendation for expanded or emergency use from WHO and acceptance by at least one National Regulatory Agency of a Member State	
	All items follow relevant WHO and ECDC guidelines and where available, WHO Commodity Package documents are used to define the technical specification of the products.		
	Ability to provide appropriate storage facilities in the Union and adequate stockpiling monitoring system.		
		to ensure appropriate procedures for adequate packaging, transport and ry of the products referred to under capacities, where needed.	
	☐ Ability to provide appropriately trained personnel to handle, and administer the products referred to under capacities.		
	Availa	bility for departure maximum 12 hours after the acceptance of the offer.	
Signat	ure and	d stamp of the responsible authority	

#### **Annex 3: Pre-financing modalities**

The aim of the pre-financing is to provide the beneficiary with a flow of cash to develop the capacity and to maintain it. The periodicity of the pre-financings has to be set in the grant agreement.

Please provide us with a clear schedule of payments necessary for the development of your capacity. This schedule should be based on your yearly expenditure.

Please fill out the table below with the pre-financing instalments you intend to request to implement the action and upload this document under "Other Annexes" in the Participant Portal.

Year	Expenditure (in EUR)	Pre-financing requested (in EUR)
2022*		
2023		
2024		
2025		
2026		
Total		

<sup>\*</sup> For the pre-financing requested for 2022, the payment may be made by the Commission in December 2021.

Please note that the total of the pre-financing will not be higher than 80% of the maximum EU contribution. The remaining amount will be calculated and paid at the end of the project, after the analysis of the final report.

If the statement on the use of the previous pre-financing payment shows that less than 70% was used, the amount of the next pre-financing instalment will be reduced by the difference between the 70% threshold and the amount used.

The beneficiary must inform the Commission by 31 December each year about the cumulative expenditure incurred from the starting date.

The Commission reserves the right to adapt the payment based on the payment appropriations available.