EMA/145300/2024
International Affairs

Call for Proposals

Grant procedure EMA/GRANT/2024/02/IA "Medicines regulatory systems strengthening in Sub-Saharan Africa"

Table of contents

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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1. EU 4 AMA: leveraging European expertise for medicines regulation in Africa

The present call for proposals no. EMA/GRANT/2024/02/IA for 'Medicines regulatory systems strengthening in Sub-Saharan Africa' provides the applicants with the terms and conditions to be respected in order to submit an application and participate to the grant procedure.

2. Context and background of the call for proposals

EMA aims to support the development of regulatory systems on the African continent and the operationalisation of the African Medicines Agency (AMA), as a result to signing with European Commission DG for International Partnerships the action 'Regional dimension and management of the Team Europe Initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+) in Africa (part II)' (OPSYSACT-61342). The collaboration between AMA and EMA will strengthen the regulatory environment for medicines in Africa, enhance the capacity of AMA, promote the adoption of common standards and guidelines, and facilitate joint assessments of medicines, which will reduce the time of regulatory processes, while ensuring faster access to safe, effective and quality-assured medicines and, ultimately, improving public health.

An important success factor for the African Medicines Agency is the presence of effective medicines regulatory systems for the supervision of medicines at national, regional and ultimately at continental level. The European Medicines Regulatory Network (EMRN) is particularly well-positioned to share its experience with counterparts on the African continent.

To foster a conducive environment for the regulation of medicines, EMA is publishing this call for proposals to the authorities in the EMRN to contribute to national and regional systems strengthening in Sub-Saharan Africa. By enabling the EMRN to share its regulatory and organizational expertise with African counterparts at both the national and regional levels this call contributes to robust regulatory systems on the African continent. Regulatory systems strengthening is considered a key component for the eventual establishment of AMA as a continental regulator.

3. Legal framework and objectives of the call

3.1. Legal framework

Article 91 of the Financial Regulation applicable to the budget of the European Medicines Agency from 1 July 2019 foresees the possibility to award grants by delegation of the Commission pursuant to Article 62(1)(c)(iv) of Regulation (EU, Euratom) 2018/1046.

Pursuant to Article 62(1)(c)(iv) of Regulation (EU, Euratom) 2018/1046, the European Commission and the European Medicines Agency have signed on 20 December 2023 a Contribution Agreement no. NDICI Africa/2023/448-916 for the implementation of objective 2: "Enhancement of EU/EMA-AU/AMA cooperation, effective coordination and good governance of health products" of the action Local manufacturing and access to vaccines, medicines and health technologies in Africa.

Pursuant to the above-mentioned Contribution Agreement, the European Medicines Agency may award grants in the performance of the activities foreseen in the Contribution Agreement, by applying its own rules and procedures.

Given the above, the present call for proposals is procedurally governed by 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.

This call is based on EMA's 2024 Work Programme for grants and procurements as presented in Annex XII of the Programming Document 2024 to 2026, available on the EMA's website.

3.2. Objectives of the call

This call is addressed only to national competent authorities for the approval, assessment and supervision of medicinal products for human use in the European Economic Area Member States and member countries (hereinafter "national competent authorities" or "NCA") and aims to achieve the following objectives:

1. Strengthen the scientific and regulatory expertise of African national regulatory authorities, looking across the lifecycle of medicinal products from development to approval to post-marketing surveillance.
2. Contribute to capacity building in one or more of the following areas:
    - Quality, non-clinical and clinical aspects of the assessment of medicinal products
    - Good manufacturing practices (GMP) inspection
    - Reliance practices
    - Pharmacovigilance
    - Clinical trial approval and regulatory oversight

3.3. Activities under this call

The activity of this grant procedure consists of financing the development and delivery of training programs aimed to regulatory professionals in Sub-Saharan African national competent authorities, including AMRH-designed Regional Centres of Regulatory Excellence (RCOREs). Grant proposals for training programs related to pharmaceutical quality for junior and/or senior assessors and junior and/or senior GMP-inspectors are encouraged.

3.3.1. Specific requirements for the activities under this call

1. It is underlined that applicants must propose to carry out the above activity that is eligible for financing under this call;
2. The activities proposed by applicants must be aimed to Sub-Saharan countries, with a national or cross-national (regional) focus;
3. The proposed activities must be implemented based on one or more of the scenarios presented in the table below. The financial amounts indicated in the scenarios are fixed and not subject to any change by the applicant. It is for the applicant to build its proposal by considering the list of scenarios below and any combination (including multiples of the same scenario) is allowed. The proposed activities in conjunction with the respective combination of scenarios reflected in the applicant's proposal must be followed during grant implementation, should the applicant be awarded a grant.

Scenarios	Elements	Fixed Budget
I: One week training in Africa (national focus)	• Training development • In-person delivery (2 persons required) • Travel EU-Africa (2 persons required) • Hotel (5 nights for 2 persons) • Daily allowance (5 days for 2 persons) • Organization of networking event • Miscellaneous related costs (e.g. visas, health insurance, etc.)	€ 26,300.00
II: One week training in Africa (cross-national focus)	• Training development • In-person delivery (2 persons required) • Travel EU-Africa (2 persons required) • Travel within Africa (5 regional participants from African NRAs required) • Hotel (5 nights for 7 persons: 2 EU trainers + 5 regional participants from African NRAs) • Daily allowance (5 days for 7 persons: 2 EU trainers + 5 regional participants from African NRAs) • Organization of networking event • Miscellaneous related costs (e.g. visas, health	€ 35,800.00

Scenarios	Elements	Fixed Budget
	insurance, etc.)	
II.a: One week training in Africa (per five additional participants already established in Africa, representing the different countries targeted by a cross-national grant application)	• Travel within Africa (5 persons required) • Hotel (5 nights for 5 persons) • Daily allowance (5 days for 5 persons)	€ 10,000.00
III: one week training in EU (five participants)	• Training development • In-person delivery (2 persons required) • Travel EU-Africa (5 participants from African NRAs required) • Hotel (5 nights for 7 persons: 2 EU trainers + 5 participants from African NRAs) • Daily allowance (5 days for 7 persons: 2 EU trainers + 5 regional participants from African NRAs) • Organization of networking event • Miscellaneous related costs (e.g. visas, health insurance, etc.)	€ 30,400.00
III. a one week training in EU (per five additional participants from Africa)	• Travel EU-Africa (5 persons required) • Hotel (5 nights for 5 persons) • Daily allowance (5 days for 5 persons) • Miscellaneous related costs (e.g. visas, health insurance, etc.)	€ 14,000.00

Scenarios	Elements	Fixed Budget
IV: one month secondment of EU expert to Africa	• Programme development • Salary costs of expert • Travel EU-Africa (1 person) • Hotel (30 nights for 1 person) • Daily allowance (30 days for 1 person) • Miscellaneous related costs (e.g. visas, health insurance, etc.)	€ 28,150.00
V: one month secondment of senior level African expert to EU	• Programme development • Travel Africa-EU (1 person) • Hotel (30 nights for 1 person) • Daily allowance (30 days for 1 person) • Miscellaneous related costs (e.g. visas, health insurance, etc.)	€ 20,700.00
VI: one day of virtual training	• Development of training • Virtual delivery • Miscellaneous related costs	€ 2,350.00

4. The implementation period of this grant is maximum 36 month(s) from the grant start date, estimated on 01/10/2024. Therefore, the proposals shall be limited to the implementation period indicated above.

3.4. Deliverables

The list of deliverables is the following:

1. A definitive project plan (maximum 10 pages) based on the project plan submitted as part of the grant application, which must include information on:
    a. Objectives
    b. Timelines

c. Milestones

d. Expected impact, including specific information on

i. Number of participants from African regulators to be trained;

ii. Number of training sessions to be conducted;

iii. Desired percentage of trainees stating an improvement of their regulatory knowledge after completion of training;

e. Complementarity to other support actions.

2. A report upon completion of each training and/or secondment activity (maximum 5 pages), which must include information on:

a. Prospective implementation activities

b. Training(s) delivered and/or secondment(s) implemented

c. Training curricula and programmes

d. Training attendance

e. Results of training evaluations by participants

f. Impact achieved as measured by specific information requested under deliverable 1.d.

3. All training materials used in the implementation of activities in original format.

4. A final report (maximum 10 pages), which must include information on:

a. Trainings delivered and/or secondments implemented

b. Objectives achieved

c. Impact achieved as measured by specific information requested under deliverable 1.d

d. Complementarity to other support actions.

3.5. Payments by EMA

a) A first pre-financing payment of 20% of the total grant to be paid within 30 calendar days following the entry into force of the grant agreement and acceptance by EMA of the definitive project plan (deliverable 1, as per section 3.4 above).

b) An interim payment of 40% of the total grant; the grant beneficiary will be able to request the interim payment after the acceptance by EMA of:

- the report upon completion of the first training or secondment activity foreseen in the proposed project plan (deliverable 2, as per section 3.4 above), and
- all training materials used in the implementation of the executed training or secondment activity (deliverable 3, as per section 3.4 above).

c) A payment of the balance linked to the acceptance by EMA of all the deliverables listed under section 3.4 above for all the trainings and secondment activities foreseen in the proposed project plan.

As stated under section 7 below, the form of the grant(s) to be awarded under this call for proposals is based on financing not linked to the costs of the relevant operations. The budget to be requested by

each applicant must be based solely on one or a combination of the scenarios and corresponding costs listed under section 3.3.1 above.

3.6. Further obligations of the grant recipient

The awarded grant beneficiary(-ies) will notify EMA without delay of any circumstances likely to adversely affect the implementation and management of the action, or to delay or jeopardise the performance of the activities.

4. Timetable

The present call for proposals shall be conducted according to the following **indicative** timetable:

	Milestones	Date/time or indicative period
(a)	Publication of the call for proposals	19/04/2024
(b)	Information meeting	May 2024
(b)	Deadline for applicants to request clarifications	09/08/2024
(c)	Deadline for EMA to reply to clarification requests	19/08/2024
(d)	Deadline for submission of proposals	31/08/2024
(e)	Evaluation period	September 2024
(f)	Information to applicants on the outcome of the evaluation	Maximum of 6 months from the deadline for submission of proposals
(g)	Signature of the grant agreement(s)	Maximum of 3 months from the date of informing the successful applicant(s)

5. Budget available

The total budget that EMA has available for this call is EUR 450,000.00 (four hundred fifty thousand EURO).

Depending on the availability of funds, the total budget for this call may be increased up to an additional EUR 450,000 (four hundred fifty thousand EURO). This should not be construed in any way as a commitment of the Agency to increase the total budget or award additional applications.

The Agency also reserves the right not to award any grant and/or to cancel the whole grant procedure at any time before the signature of the grant agreement without any compensation to be paid to the applicant.

6. Roles and tasks of applicant(s)

6.1. Entities involved in the activities subject to the application

The application shall clearly identify the entities (legal and/or natural persons) to be involved in the activities subject to the application, being the applicant (including **coordinator and co-applicants**) as well as any third parties, such as **affiliated entities and subcontractors** and their contributions to the implementation of the application under the grant agreement. Parties' participation in the project will be subject to the requirements as laid down in the present call for proposals.

6.2. Single applicant

In case the proposal is submitted by a single applicant, it will be considered as a mono-beneficiary grant agreement, if the application is selected for award.

6.3. Coordinator

If the proposal is submitted by a group of several co-applicants, they will form a consortium and will become consortium members. The consortium members should choose amongst them a lead organisation, referred to as the "Coordinator".

The coordinator submits the proposal on behalf of the consortium and will be the intermediary for all communication between the co-beneficiaries and EMA as well as responsible for supplying all documents and information to EMA in due time upon request.

The grant agreement shall be signed by the coordinator of the successful consortium, provided that a mandate (Annex IV of the grant agreement) has been provided to it by each co-applicant (multi-beneficiaries grant agreement). Such mandates shall be annexed to the grant agreement.

The coordinator will also be responsible for distribution of payments received from EMA to the co-beneficiaries.

6.4. Co-applicants

Each co-applicant will be considered as co-beneficiary if the proposal is selected for award. Before signature of the grant agreement, all applicants within the consortium shall agree upon appropriate arrangements between themselves for the proper performance of the specific actions.

Co-applicants shall immediately inform the coordinator of any event which can substantially affect or delay the implementation of the action. The coordinator will inform EMA in accordance with the grant agreement and will ensure compliance with all the terms and conditions provided in the draft grant agreement.

The coordinator and all co-applicants forming the consortium must satisfy the eligibility criteria.

6.5. Affiliated entities

Legal persons having a legal or capital link with the applicant(s), which is neither limited to the action nor established for the sole purpose of its implementation, may take part in the action as affiliated entities, and may declare eligible costs. For that purpose, the applicant(s) shall identify such affiliated entities in the application forms and in the proposal.

Each affiliated entity shall have to comply with the same eligibility and non-exclusion criteria as those applying to the applicant(s) and submit the same forms.

6.6. Subcontractors

Subcontracting refers to contracts concluded for the externalisation of specific tasks or activities which do not form a core part of the proposed action.

The beneficiary remains solely responsible for the implementation of the action.

Please note that the applicant must have the necessary operational capacity to perform the project itself.

Subcontracting of specific tasks or activities (i.e. the externalisation) which form part of the action as described in the proposal must satisfy the following conditions:

1. recourse to subcontracting is justified because of the nature of the action and what is necessary for its implementation;
2. any recourse to subcontracting, if not provided for in description of the action, is communicated by the beneficiary(-ies) and approved by the Agency as per Article II.11.1(d) of the draft grant agreement;
3. the subcontract is awarded to the entity offering best value for money or the lowest price (as appropriate), avoiding conflicts of interests;
4. the beneficiary ensures that certain conditions applicable to it, as stipulated in the draft grant agreement (e.g. visibility, confidentiality etc.) are also applicable to subcontractors.

7. Grant principles

The financial support provided by EMA under this call is a grant governed by the Financial Regulation referred to under section 3.1. Accordingly, the grant awarded following this call must comply with the following principles:

- the form of grant awarded under this call is based on financing not linked to the costs of the relevant operations in accordance with Article 125(1)(a) of the Financial Regulation. Grants financed in this way require the achievement of results measured by reference to previously set milestones or through performance indicators.
- the present call comes with an innovative and simplified grant management, where the grant amounts paid to the beneficiary are based on the pre-defined sums which are not linked to the actual costs of the action. This means that there is no need for co-financing from the beneficiary, and no need for completion of estimated budgets or timesheets to record the work. The agreed sums are set at a level designed to stimulate the mutually convenient partnership creation. The payment of agreed sums from EMA will be carried out based on the acceptance by EMA of the delivered work.
- Non-retroactivity: A grant may be awarded for a project which has already begun only where the applicant can demonstrate in the grant proposal the need to start the action before the grant agreement is signed, in accordance with Article 193 of the Financial Regulation. The tasks entrusted by EMA should not be performed before the signature of the grant Agreement.
- Use of content: EMA shall have the right to use for institutional purposes any work product or deliverables produced through actions under this call; institutional purposes shall mean any non-commercial purpose related to the strengthening of national and regional systems in

Sub-Saharan Africa. More information on EMA's right to use the deliverables can be found in the draft grant agreement under Annex V to the present call for proposals.

8. Publicity

All beneficiaries are expected to follow the rules on visibility of EMA funding set out in Article II.8 of the draft grant agreement.

According to Article 38 of the Financial Regulation EMA is bound to publish information on recipients of its grants at its website. Such publication shall take place no later than 30 June of the year following the financial year in which the grants were awarded and shall cover these data of the beneficiaries:

- name of the beneficiary;
- address of the beneficiary;
- subject of the grant;
- amount awarded.

9. Data protection

The Agency processes personal data in accordance with *Regulation (EU) 2018/1725 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data*.

Details concerning the processing of your personal data are available on the privacy statement on the Agency's website at: https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-data-protection-notice-grant-procedures_en.pdf

10. Evaluation and award

The evaluation of the proposal will consist of the following elements:

- Verification of admissibility requirements (section 11);
- Verification of eligibility criteria (section 12);
- Verification of non-exclusion of the applicant on the basis of the exclusion criteria (section 13);
- Evaluation of the proposal on the basis of the award criteria (section 14).

The Agency will evaluate the abovementioned elements in the order that it considers to be the most appropriate. If the evaluation of one or more elements demonstrates that there are grounds for rejection, the proposal will be rejected and will not be subjected to further full evaluation.

The evaluation will be based on the information and evidence contained in the proposal and, if applicable, on additional information and evidence provided at the request of the Agency during the procedure. If any of the declarations or information provided proves to be false, the Agency may impose administrative sanctions (exclusion or financial penalties) on the entity providing the false declarations/information.

For the purposes of the evaluation related to exclusion criteria the Agency may also refer to publicly available information, in particular evidence that it can access on a national database free of charge.

11. Admissibility requirements

In order to be admissible, the proposal must be:

- sent no later than the deadline for submitting proposals referred to in section 4;
- submitted in writing (see section 16), using the application form; and
- drafted in one of the EU official languages; however, as EMA's working language is English, the submission of proposal in English would speed up the evaluation process.

12. Eligibility criteria

12.1. Requirement

Proposals may only be submitted by national competent authorities for the approval, assessment and supervision of medicinal products for human use in the European Economic Area Member States and member countries (European medicines regulatory network, EMRN)."

12.2. Evidence required

The following documents must be submitted:

1. Administrative data for grant proposal (**Annex I**)
2. Vendor identification form (**Annex II**)

13. Exclusion criteria

The objective of the exclusion criteria is to assess whether the applicant is in any of the exclusion situations listed in Article 136(1) of Regulation (EU, Euratom) 2018/1046.

If the applicant is found to be in an exclusion situation, it will be rejected.

As evidence of non-exclusion, the applicant shall provide with its proposal a declaration on their honour (see **Annex III**), duly signed and dated by an authorised representative, stating that they are not in one of the situations of exclusion listed in this Annex.

The initial verification of non-exclusion will be done on the basis of the submitted declaration and consultation of the European Union's Early Detection and Exclusion System. The documents mentioned as supporting evidence in the Declaration on Honour need to be provided whenever requested and where this is necessary to ensure the proper conduct of the procedure within a deadline given by EMA.

14. Qualitative Award criteria

The award criteria serve to assess the quality of the proposal in relation to the objectives of the call. The following award criteria shall apply to the present call:

No.	Qualitative award criterion	Maximum points available	Minimum points, which must be achieved
1	**Project plan and relevance:** • description of the proposed action,	**35**	**23**

No.	Qualitative award criterion	Maximum points available	Minimum points, which must be achieved
	including methodology employed to achieve one or more of the objectives listed under section 3.2; • an outline of the high-level learning objectives envisaged to be achieved by the proposed training and/or secondment activities; • a description of the assessment method for measuring the skills acquired through the proposed training and/or secondment activities; • a description of the measures taken by the applicant to ensure that the proposed action is driven by identified need(s) for intervention and that it will not overlap with any other actions addressing the same need(s); • expected impact and corresponding key performance indicators to measure the impact of the proposed action.		
2	**Appropriateness of the work organisation, planning, resources and methodology.** • description of the actors in the action, the proposed experts for training and/or secondment and the distribution of the tasks amongst them; • description of the timelines for the implementation and completion of the action, expected outcomes and deliverables.	**20**	**12**
3	**Quality assurance** • description of quality assurance measures proposed for the project to guarantee high quality of deliverables (e.g quality of training delivery, satisfaction survey); • inclusion of risk register including assessment if risks are being	**20**	**12**

No.	Qualitative award criterion	Maximum points available	Minimum points, which must be achieved
	mitigated/managed or tolerated.		
4	**Impact** • description of the envisaged long-term impact of results on regulatory system in the recipient country/region, including sustainability of results after funding ends; • description of proposed measures to minimise ecologic footprint.	**25**	**13**
	TOTAL	**100**	**60**

To be considered for award, a proposal must:

- score a total minimum of 60 out of an overall maximum of 100 points
- score at least the minimum threshold indicated for each criterion in the table above.

The applicants are requested to reply to the above qualitative award criteria by filling the template 'Award criteria questionnaire', (**Annex IV**).

15. Process following the conclusion of the evaluation

At the end of the evaluation:

1. the proposal(s) that have achieved the minimum scores as identified in section 14 will be ranked based on the total points achieved;
2. the Agency will proceed to propose for award the 1st ranked proposal, followed by the 2nd etc. until the maximum budget for this call (as indicated under section 5) has been exhausted;
3. any proposal(s) that have achieved the minimum scores but have not been proposed for award due to budget exhaustion (as per the process under point 2 above), will be placed on a reserve list; should additional budgetary appropriations become available, the respective applicant(s) will be informed about the potential award of a grant, according to their ranking on the reserve list;
4. any proposal(s) that have not achieved the minimum scores as identified in section 14 will be rejected.

All the applicants will be notified of the outcome, once the evaluation has been finalised.

If proposed for award, EMA reserves the right to invite the applicant to adapt its proposal based on the evaluation committee's comments in accordance with article 200(5) of the Financial Regulation.

Following the successful conclusion of the adaptation phase, the award decision will be taken by EMA. Subsequently, the grant agreement will be prepared.

16. Submission of proposal

16.1. Submission completeness checklist

The proposal must be submitted along with all the requested annexes and the administrative data for grant application form signed by a duly authorised legal representative of the applicant.

The applicant should be precise and provide enough detail to ensure the technical proposal is well described and addressing all the award criteria by following the template under Annex IV.

By submitting a proposal, the applicant accepts the procedures and conditions described in this call and in the documents referred to in it.

The below checklist is designed to help the applicant to collect the documents in a structured way before submission of the proposal to EMA.

Type of criteria	Documents required	Relevant section of the call
Admissibility requirements	N/A	Section 11
Eligibility criteria	1. Administrative data for grant application (template in Annex I to the Call for Proposals) 2. Vendor identification form (template in Annex II to the Call for Proposals)	Section 12
Exclusion criteria	Declaration on honour on the exclusion criteria (template in Annex III to the Call for Proposals)	Section 13
Award criteria	1. Technical proposal covering award criteria (template in Annex IV)	Section 14

16.2. Submission modalities

The applicant can submit its proposal electronically **to the following email address only**: ema-grant-2024-02-ia@ema.europa.eu. **It is explicitly underlined that proposals must not be sent to any other email addresses.**

Submission should take place not later than 12:00 pm (Amsterdam time) on the deadline for submission of proposals indicated in section 4, i.e. 31/08/2024.

Annex I to Call for Proposals

Administrative data for grant applications

Section 1: Information on the grant applicant	
Official name in full:	
Legal form:	
Registered Business Address including country of registration:	
Company registration number (if applicable):	
VAT registration number (if applicable):	
Section 2.1: Contact details of person responsible for the application **Please give details of the person representing the applicant to whom any queries relating to the answers to the grant procedure should be addressed:**	
Contact Name:	
Contact Title:	
Telephone Number:	
Address for correspondence (if different to that given under Section 1 above):	
E-mail Address: NB all communication by EMA on the grant procedure shall be executed only by e-mail.	

Section 2.2: Contact details of the legal representative **Please give details of the legal representative of the applicant, i.e. the person who is authorised to sign the grant agreement, in case of award:**	
Contact Name:	
Contact Title:	
Telephone Number:	
Address for correspondence (if different to that given under Section 1 above):	
E-mail Address: NB all communication by EMA on the grant procedure shall be executed only by e-mail.	
Section 3: Identity of the affiliated entities (if applicable) **This section should be filled in only in case affiliated entities are included in the grant proposal (see section 6.5 of the Call for Proposals)**	
Official name in full:	
Legal form:	
Registered Business Address including country of registration:	
Company registration number (if applicable):	
VAT registration number (if applicable):	
Legal or capital link with the applicant, if applicable: **The affiliated entity should provide a short description of the legal or capital link with the applicant and provide the statutory documents and/or consolidated accounts.**	
Section 4: Additional EU funding	

Has the applicant or any of the affiliated entities received or applied for any Union funding for the same action or part of the action or for its functioning during the same financial year?	
If yes, please fill in all the following information for each of the applications or obtained grants in the current or previous years (add columns if necessary):	
Title of the action (or part of the action)	
Union Programme concerned	
Union Institution or Body/Agency to which the application was submitted or which took the award decision	
Year of award or application and duration of the operation	
Value of the application, grant or other funding	

Date:

Signature of authorised representative:

(Print name):

Position in company:

Representing (name of applicant):

Annex II to Call for Proposals

Vendor identification form

(separate document)

Annex III to Call for Proposals

Declaration of honour on exclusion criteria

Call for Proposals reference number:

Call for Proposals title:

The undersigned insert name of signatory

(*only for natural persons*) representing himself or herself	(*only for legal persons*) representing the following legal person:
ID or passport number: (**'the person'**)	Full official name: Official legal form: Statutory registration number**:** Full official address: VAT registration number: (**'the person'**)

A. Declaration on honour on exclusion criteria

The person is not required to fill in this Part A of the declaration (Declaration on honour on exclusion criteria) if the same declaration has already been submitted for the purposes of another award procedure of the same contracting authority[1], provided the situation has not changed, and that the time that has elapsed since the issuing date of the declaration does not exceed one year.

In this case, the signatory declares that the person has already provided the same declaration on exclusion criteria for a previous procedure and confirms that there has been no change in its situation:

Date of the declaration	**Full reference to previous procedure**

I – Situations of exclusion concerning the person

(1) declares that the person is in one of the following situations:	YES	NO
a) it is bankrupt, subject to insolvency or winding-up procedures, its assets are being administered by a liquidator or by a court, it is in an arrangement with creditors, its business activities are suspended or it is in any analogous situation arising from a similar procedure provided for under Union or national law;	☐	☐
b) it has been established by a final judgement or a final administrative decision that the person is in breach of its obligations relating to the payment of taxes or social security contributions in accordance with the applicable law;	☐	☐

[1] The same EU institution, agency, body or office.

c) it has been established by a final judgement or a final administrative decision that the person is guilty of grave professional misconduct by having violated applicable laws or regulations or ethical standards of the profession to which the person belongs, or by having engaged in any wrongful conduct which has an impact on its professional credibility where such conduct denotes wrongful intent or gross negligence, including, in particular, any of the following:		
(i) fraudulently or negligently misrepresenting information required for the verification of the absence of grounds for exclusion or the fulfilment of eligibility or selection criteria or in the performance of a contract or an agreement;	☐	☐
(ii) entering into agreement with other persons or entities with the aim of distorting competition;	☐	☐
(iii) violating intellectual property rights;	☐	☐
(iv) attempting to influence the decision-making process of the contracting authority during the award procedure;	☐	☐
(v) attempting to obtain confidential information that may confer upon it undue advantages in the award procedure***;***	☐	☐
d) it has been established by a final judgement that the person is guilty of any of the following:		
(i) fraud, within the meaning of Article 3 of Directive (EU) 2017/1371 and Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995;	☐	☐
(ii) corruption, as defined in Article 4(2) of Directive (EU) 2017/1371 or active corruption within the meaning of Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union, drawn up by the Council Act of 26 May 1997, or conduct referred to in Article 2(1) of Council Framework Decision 2003/568/JHA, or corruption as defined in other applicable laws;	☐	☐
(iii) conduct related to a criminal organisation, as referred to in Article 2 of Council Framework Decision 2008/841/JHA;	☐	☐
(iv) money laundering or terrorist financing, within the meaning of Article 1(3), (4) and (5) of Directive (EU) 2015/849 of the European Parliament and of the Council;	☐	☐
(v) terrorist offences or offences related to terrorist activities as well as of inciting, aiding, abetting or attempting to commit such offences as defined in Articles 3, 14 and Title III of Directive (EU) 2017/541 of the European Parliament and of the Council of 15 March 2017 on combating terrorism;	☐	☐
(vi) child labour or other offences concerning trafficking in human beings as referred to in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council;	☐	☐
e) it has shown significant deficiencies in complying with the main obligations in the performance of a contract or an agreement financed by the Union's budget, which has led to its early termination or to the application of liquidated damages or other contractual penalties, or which has been discovered following checks, audits or investigations by a contracting authority, the European Anti-Fraud Office (OLAF) or the Court of Auditors;	☐	☐
f) it has been established by a final judgment or final administrative decision that the person has committed an irregularity within the meaning of Article 1(2) of Council Regulation (EC, Euratom) No 2988/95;	☐	☐
g) it has been established by a final judgment or final administrative decision that the person has created an entity in a different jurisdiction with the intent to circumvent fiscal, social or any other legal obligations in the jurisdiction of its registered office, central administration or principal place of business.	☐	☐
h) (*only for legal persons*) it has been established by a final judgment or final administrative decision that the person has been created with the intent referred to	☐	☐

in point (g).		
(2) declares that, for the situations referred to in points (1) (c) to (1) (h) above, in the absence of a final judgement or a final administrative decision, the person is[2]:	YES	NO
i. subject to facts established in the context of audits or investigations carried out by the European Public Prosecutor's Office, the Court of Auditors, or the internal auditor, or any other check, audit or control performed under the responsibility of an authorising officer of an EU institution, of a European office or of an EU agency or body;	☐	☐
ii. subject to non-final judgments or non-final administrative decisions which may include disciplinary measures taken by the competent supervisory body responsible for the verification of the application of standards of professional ethics;	☐	☐
iii. subject to facts referred to in decisions of entities or persons being entrusted with EU budget implementation tasks;	☐	☐
iv. subject to information transmitted by Member States implementing Union funds;	☐	☐
v. subject to decisions of the Commission relating to the infringement of Union competition law or of a national competent authority relating to the infringement of Union or national competition law;	☐	☐
vi. informed, by any means, that it is subject to an investigation by the European Anti-Fraud office (OLAF): either because it has been given the opportunity to comment on facts concerning it by OLAF, or it has been subject to on-the-spot checks by OLAF in the course of an investigation, or it has been notified of the opening, the closure or of any circumstance related to an investigation of the OLAF concerning it.	☐	☐

II – Situations of exclusion concerning natural or legal persons with power of representation, decision-making or control over the legal person and beneficial owners

Not applicable when 'the person' is a natural person, a Member State or a local authority. In all other cases to be filled in by all involved entities.

(3) declares that a natural or legal person who is a member of the administrative, management or supervisory body of the person, or who has powers of representation, decision or control with regard to the person (this covers e.g. company directors, members of management or supervisory bodies, and cases where one natural or legal person holds a majority of shares), or a beneficial owner of the person (as defined by point 6 of Article 3 of Directive (EU) No 2015/849) is in one of the following situations:	YES	NO	N/A
Situation (1)(c) above (grave professional misconduct)	☐	☐	☐
Situation (1)(d) above (fraud, corruption or other criminal offence)	☐	☐	☐
Situation (1)(e) above (significant deficiencies in performance of a contract)	☐	☐	☐
Situation (1)(f) above (irregularity)	☐	☐	☐

[2] The declaration under this point (2) is voluntary and it cannot have adverse legal effect on the economic operator until the conditions of Article 141(1) (a) FR are met.

Situation (1)(g) above (creation of an entity with the intent to circumvent legal obligations)	☐	☐	☐
Situation (1)(h) above (person created with the intent to circumvent legal obligations)	☐	☐	☐

III – Situations of exclusion concerning natural or legal persons assuming unlimited liability for the debts of the legal person

Not applicable when 'the person' is a natural person, a Member State, a local authority or legal persons with limited liability. In all other cases to be filled in by all involved entities.

(4) declares that a natural or legal person that assumes unlimited liability for the debts of the person is in one of the following situations:	YES	NO	N/A
Situation (a) above (bankruptcy)	☐	☐	☐
Situation (b) above (breach in payment of taxes or social security contributions)	☐	☐	☐

IV – Other grounds for rejection from this procedure

(5) declares that the person:	YES	NO
(a) was previously involved in the preparation of the documents used in this award procedure, where this entailed a breach of the principle of equality of treatment including distortion of competition that cannot be remedied otherwise.	☐	☐

V – REMEDIAL MEASURES

If the person declares one of the situations of exclusion listed above, it may indicate remedial measures it has taken to remedy the exclusion situation, in order to allow the authorising officer to determine whether such measures are sufficient to demonstrate its reliability. This may include e.g. technical, organisational and personnel measures to prevent further occurrence, compensation of damage or payment of fines or of any taxes or social security contributions. The relevant documentary evidence, which illustrates the remedial measures taken, must be provided in annex to this declaration. This does not apply for situations referred in point (1) (d) of this declaration.

VI–evidence on exclusion criteria

Upon request only and within the time limit set by the EMA, the person must provide the following evidence concerning the person or entity itself and the natural or legal persons on whose capacity the person intends to rely, and concerning the natural or legal persons which assume unlimited liability for the debt of the person:

- For situations described in points (1): (a), (c), (d), (f), (g) and (h) above, a recent extract from the judicial record or, failing that, an equivalent document recently issued by a judicial or administrative authority in the country of establishment of the person showing that those requirements are satisfied.
- For the situations described in point (1) (a), (b), recent certificates issued by the competent authorities of the the country of establishment. These documents must provide evidence covering all taxes and social security contributions for which the person is liable, including for example, VAT, income tax (natural persons only), company tax (legal persons only) and social security contributions. Where any document described above is not issued in the country of establishment, it may be replaced by a sworn statement made before a judicial authority or notary or, failing that, a solemn

statement made before an administrative authority or a qualified professional body in its country of establishment.

The person is not required to submit the evidence if it has already been submitted for another award procedure of the same contracting authority[3]. The documents must have been issued no more than one year before the date of their request by the contracting authority and must still be valid at that date.

The signatory declares that the person has already provided the documentary evidence for a previous procedure and confirms that there has been no change in its situation:

Document	Full reference to previous procedure
Insert as many lines as necessary.	

The person is not required to submit the evidence if it can be accessed on a national database free of charge.

The signatory declares that the following internet address of the database/identification data provide access to the evidence required.

Internet address of the database	Identification data of the document
Insert as many lines as necessary.	

B. Declaration on honour on eligibility

The person submitting an application for the above procedure:

(6) declares that the applicant:	YES	NO
(a) is fully eligible in accordance with the criteria set out in the Call for Proposals	☐	☐
(b) **has not** received any other Union funding to carry out the action subject of this grant application and commits to declare immediately to the EMA any other such Union funding it would receive until the end of the action	☐	☐

C. Declaration on honour on established debt to the union

The person submitting an application for the above procedure:

(9) declares that the person	YES	NO
(a) has an established debt to the Union, European Atomic Energy Community or an executive agency when the latter implements the Union budget.	☐	☐

The person must immediately inform the EMA of any changes in the situations as declared.

The person may be subject to rejection from this procedure and to administrative sanctions (exclusion or financial penalty) if any of the declarations or information provided as a condition for participating in this procedure prove to be false.

Full name:
Date:
Signature:

[3] The same EU institution, agency, body or office.

The declaration is to be signed with:

1. Electronic signature (recommended option):

In case you have the possibility to sign the declaration using a qualified electronic signature (QES), please have it signed electronically by your authorised representative(s). Please note that only the qualified electronic signature (QES) within the meaning of Regulation (EU) No 910/2014 (eIDAS Regulation) will be accepted.

Before sending back your electronically signed document, please check the signature and validity of the certificate with one of the following tools:

- *DSS Demonstration validation tool available at https://ec.europa.eu/cefdigital/DSS/webapp-demo/validation can help you check the validity of a certificate by indicating the number and type of valid signatures in a document.*
- *EU Trusted List Browser can be consulted in order to check whether the electronic signature provider and the trust service it provides are part of European Union Trusted List: https://esignature.ec.europa.eu/efda/tl-browser/#/screen/home*

To make sure you use a QES compliant to eIDAS Regulation, you need to check that both the service provider and the qualified certificate generation service used are included in the EU Trusted List Browser.

2. Handwritten signature:

In case you do not have the possibility to sign the declaration using a qualified electronic signature (QES), please fill it in electronically, then print it and have it signed and dated by your authorised representative(s) using a hand-written signature.

Annex IV to Call for Proposals

Award criteria questionnaire

Please use the "Response" section of the table below for your response to the criteria or to list documents provided in response to the criteria.

Ref.	Question	Response
1	**Project plan and relevance:** • description of the proposed action, including methodology employed to achieve one or more of the objectives listed under section 3.2; • an outline of the high-level learning objectives envisaged to be achieved by the proposed training and/or secondment activities; • a description of the assessment method for measuring the skills acquired through the proposed training and/or secondment activities; • a description of the measures taken by the applicant to ensure that the proposed action is driven by identified need(s) for intervention and that it will not overlap with any other actions addressing the same need(s); • expected impact and corresponding key performance indicators to measure the impact of the proposed action.	
2	**Appropriateness of the work organisation, planning, resources and methodology.** • description of the actors in the action, the proposed experts for training and/or secondment and the distribution of the tasks amongst them; • description of the timelines for the implementation and completion of the action, expected outcomes and deliverables.	

Ref.	Question	Response
3	**Quality assurance** • description of quality assurance measures proposed for the project to guarantee high quality of deliverables (e.g quality of training delivery, satisfaction survey); • inclusion of risk register including assessment if risks are being mitigated/managed or tolerated.	
4	**Impact** • description of the envisaged long-term impact of results on regulatory system in the recipient country/region, including sustainability of results after funding ends; • description of proposed measures to minimise ecologic footprint.	

Annex V to Call for Proposals

Draft Grant Agreement

(separate document)