

# EU 4 AMA: leveraging European expertise for medicines regulation in Africa



Information session, 22 May 2024

Call for proposals (EMA/GRANT/2024/02/IA)



# Agenda- Call for proposals

**Objectives and activities**



**Specific Requirements**



**Deliverables**



**Organisational and financing aspects**



**Evaluation and timetable**



## Objectives:

- 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.
- Contribute to capacity building: quality, (non-) clinical, GMP, reliance practices, PV, clinical trials.

## Eligible activity:

- Development and delivery of **training programs** to regulatory professionals in Sub-Saharan Africa NCA's

## **Fixed** scenarios for implementation of activity with a **fixed budget**:

- One-week training in Africa (national focus)
- One-week training in Africa (cross-national focus)
- One-week training in Africa (per five additional participants, established in Africa, representing different countries identified in a cross-national application)
- One-week training in EU
- One-week training in EU (per five additional participants from Africa)
- One month secondment of EU expert to Africa
- One month secondment of senior level African expert to EU
- One day of virtual training



Your proposal must:

- Cover the one eligible activity
- Ensure the objectives are achieved
- Aimed to Sub-Saharan countries, with a national or cross-national (regional) focus
- Be based exclusively on one or more of the implementation scenarios:
  - you are free to combine the scenarios as you wish
  - whatever combination is proposed **MUST** be followed during the implementation of the grant



- **Definitive project plan** based on the project plan submitted with your proposal
- **Report upon completion of each training and/or secondment activity**
- **Training materials used in the implementation of activities**
- **Final report**

## How do we calculate the amount of each grant to be awarded?

- ❑ Depending on the specific implementation scenarios you have proposed → sum of the fixed amount of each scenario
- ❑ Taking into consideration the maximum budget of EUR 450,000 available for this call
- ❑ In principle, the amount requested by each proposal (based on the proposed implementation scenarios) will be awarded → EMA reserves the right to invite successful applicants to adapt their proposal

**Single applicant** → one NCA submits a proposal alone

**Multiple applicants** → two or more NCAs submit a proposal together

- One of the group's NCAs must be appointed as coordinator who will be in charge of:
  - ❑ submitting the grant proposal on behalf of the group
  - ❑ submitting deliverables on behalf of the group
  - ❑ receiving payments in its bank account and distributing them to each member of the group
  - ❑ signing any documents on behalf of the group
- Each NCA will be jointly and severally liable for the implementation
- Every NCA part of the group must satisfy the eligibility and exclusion criteria

**Affiliated entities** → legal persons with a legal or capital link with the applicant which is not established for the purpose of this grant

**Subcontracting** → contracts between an applicant and a third entity to perform certain activities

- must be identified in the proposal
- certain obligations under the grant agreement apply also to the subcontractor

## What do we evaluate and what should you do?

### Proposal admissibility

Submit proposal by  
31/08/2024 12:00 pm CET.

Submit proposal in writing,  
using the published forms.

Prepare proposal in one of the  
EU official languages preferably  
in English.

### Eligibility criteria

Proposal must be submitted  
only by NCAs for approval,  
assessment and supervision of  
medicinal products in the EEA.

Your authorised representative  
must fill in and sign **Annex I,  
administrative data (all  
NCAs)** and **Annex II, vendor  
identification form (only  
sole applicant/coordinator)**.

### Exclusion criteria

Your authorised representative  
must fill in and sign **Annex  
III, declaration on honour  
(all NCAs)**.

### Award criteria – proposal's quality

Complete **Annex IV, award  
criteria questionnaire**.

Explain how your proposal meets  
each qualitative award criterion.

No additional information can be  
submitted during evaluation.

**Do not include** hyperlinks or  
external references. **We can  
evaluate only what is  
submitted with your proposal.**

Avoid repeating criterion text;  
**provide detailed information.**

Scores on **award criteria**  
determine the winners.

**Must** achieve minimum criterion  
scores and a total of at least **60  
points**.



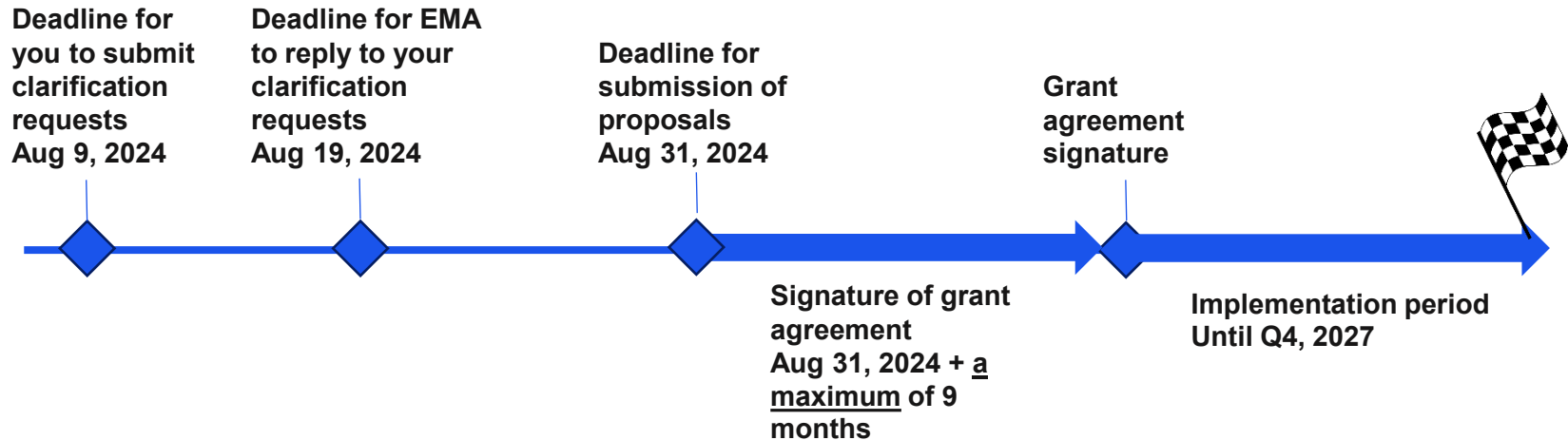


- Proposals with the **minimum criterion score and 60 points** overall are considered successful.
- Successful proposals are **ranked by total scores**.
- Grants are awarded starting with the highest-ranked proposals **until the EUR 450,000 budget is exhausted**.
- Successful proposals that cannot be awarded due to **lack of budget** are placed on a **reserve list** and contacted if additional funds become available.
- Awarded applicants **must sign** the grant agreement (**Annex V**); this document cannot be modified



- **The grant is built on “financing not linked to costs” – this means that:**
  - You must only submit the deliverables requested in the call in order to request a payment → not necessary to collect other supporting evidence (e.g. timesheets of hours spent on the project)
  - EMA will pay the exact fixed amount per implementation scenario, provided that the submitted deliverables can be accepted
- **Pre-financing payment**
  - 20% of the total grant
  - You must submit a definitive project plan, based on the plan submitted with your proposal
  - EMA will execute the payment within 30 days of accepting the definitive project plan
- **Interim payment**
  - You must submit:
    - ❑ the report upon completion of the first training/secondment activity foreseen in your project plan
    - ❑ all training materials used in the implementation of the executed training/secondment activity
  - EMA will calculate the payment amount as follows: (40% of the total grant) – (total amount of pre-financing paid, i.e. 20% of the total grant)
- **Payment of the balance**
  - You must submit all the deliverables (i.e. report per training/secondment activity, training materials for each training/secondment activity, and final report) for all the remaining trainings/secondment activities foreseen in your project plan
  - EMA will calculate the payment amount as follows: (total amount of grant) – (sum of each payment previously executed)

## Timeline and logistics for submission



### Submission logistics:

- You must submit your proposal electronically via email to [ema-grant-2024-02-ia@ema.europa.eu](mailto:ema-grant-2024-02-ia@ema.europa.eu)
- You must submit your proposal by 31 August 12:00 CET (Amsterdam time)
- We will not be able to accept proposals submitted in any other way
- Any communications during the evaluation must go through [ema-grant-2024-02-ia@ema.europa.eu](mailto:ema-grant-2024-02-ia@ema.europa.eu)