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SCIENCE MEDICINES HEALTH

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Questions and answers relating to Grant Procedure no. EMA/GRANT/2024/02/IA 'Medicines regulatory systems strengthening in Sub-Saharan Africa'

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Questions and answers

TABLE 1

No.	Question	Answer
1.	<p>Subject: Information meeting</p> <p>Description: with regards to the call for proposal specified in the subject, to enquire about the "Information meeting" scheduled in May (as per the Timetable on page 9), could you please inform us whether a date has already been set for such meeting and whether it will be a virtual or a face-to-face event?</p>	<p>Please refer to the email titled "AMA: Call for Proposals EMRN - Information Session" that was sent on May 8, 2024. The session will take place on May 22 from 10:00h to 11:00h (CET).</p>
2.	<p>Subject: Information meeting</p> <p>Description: Is it allowed to share invitation of the information session with my colleagues? Can they participate?</p>	<p>Yes.</p>
3.	<p>Will the session take place at 10 am CET, as indicated below, which would be 9 am CEST?</p> <p>NB: Please note that, due to a clerical error, a wrong question was previously published under no.3. This has now been corrected. For the avoidance of doubt, the answer to the question previously indicated under no.3 was already answered by EMA under no.4 below.</p>	<p>The meeting will take place at 10 am Amsterdam time; CET and CEST time zones are currently the same in the Netherlands, i.e. 10am CET is also 10am CEST in the Netherlands.</p>
4.	<p>The grants will finance training programmes in Reliance practices, which trainings are all meant by this?</p> <p>NB: Please note that, due to a clerical error, a wrong question was previously published under no.4. This has now been corrected. For the avoidance of doubt, the answer to the question previously indicated under no.4 was already answered by EMA under no.5 below.</p>	<p>Reliance is understood as the act whereby the national regulatory authority (NRA) in one jurisdiction may take into account and give significant weight to assessments performed by another NRA or trusted institution, or to any other authoritative information in reaching its own decision. An activity fostering to this practice will be understood contributing to the grant's objective.</p> <p>In addition to Reliance practices, the activities developed by applicants under the call for proposals have as objective to contribute to capacity building in one or more of the following areas:</p>

No.	Question	Answer
		<ul style="list-style-type: none"> • Quality, non-clinical and clinical aspects of the assessment of medicinal products; • Good manufacturing practices (GMP) inspection; • Pharmacovigilance; • Clinical trial approval and regulatory oversight.
5.	<p>Is there already a project plan / strategy for the overall project (what is the initial situation, what is to be achieved in what time, which projects are required, what goal is to be achieved at the end, how is success measured?)</p>	<p>EMA has signed an agreement with the European Commission’s Directorate-General for International Partnerships (INTPA) in December 2023 to support the setting up of the African Medicines Agency.</p> <p>The agreement defines three main priorities:</p> <ul style="list-style-type: none"> • Support the operationalisation of AMA and the framework for collaboration among African regulators. • Strengthen the scientific and regulatory expertise of the African regulatory network. • Align the efforts of the European Medicine Regulatory Network supporting African regulators. <p>These priorities have been integrated in a logical framework, defining the expected results, baseline and targets. Whilst the agreement between EMA and INTPA is a non-public document, a broad outline of this strategy is provided via: https://www.ema.europa.eu/en/partners-networks/international-activities/multilateral-coalitions-initiatives/african-medicines-agency-african-union#ema-and-european-support-64382.</p>
6.	<p>In section 3.3.1 of the call for proposals, different scenarios for proposed activities are listed.</p> <p>We would be very interested in two of the listed scenarios (one week training in Africa (national focus) and one month secondment of EU expert to Africa).</p>	<p>Applicants can combine the scenarios as they wish (e.g. combination of different scenarios and/or multiples of the same scenario).</p>

No.	Question	Answer
	Therefore, the question arose, if one National Competent Authority can submit proposals for several activities (in our case for two scenarios) or whether this call is limited to one proposal including one scenario per NCA?	<p>Depending on proposed combination by the applicant, this must also be followed during the implementation of the grant.</p> <p>The proposed activities in response to the call for proposals should be based exclusively on one or more of the implementation scenarios listed under section 3.3.1.</p>
7.	Regarding setting up the project, how can we engage, involve, and pay African institutions (Regional Centres of Regulatory Excellence – “RCOREs”) in the project, given that the call only addresses European institutions?	<p>NB: It is explicitly underlined that the reply to the present question concerns the situation whereby an applicant would like to involve RCOREs in the development and delivery of training programmes. It does not concern the situation whereby RCOREs would be the recipients of training programmes, which is addressed in the reply to question no.12.</p> <p>According to the section 3.2 of the call for proposals document (“Objectives of the call”), <i>“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” (emphasis added).</i></p> <p>However, the call allows for the involvement of other entities as well (see section 6 of the call for proposals document). Therefore, should an interested applicant (including coordinator and co-applicants) consider including third parties, such as African institutions (Regional Centres of Regulatory Excellence – “RCOREs”), then it should assess if it falls under section 6.5 (“Affiliated entities”) or section 6.6 “Subcontractors” of the call for proposals document.</p> <p>Please note that for an affiliated entity, the eligibility criterion indicated in section 12.1 of the call for proposals document, must apply to the entity (see section 6.5 that states <i>“Each affiliated entity shall have to comply with the same eligibility and non-exclusion criteria as those applying to the</i></p>

No.	Question	Answer
		<p><i>applicant(s) and submit the same forms.</i>”). Therefore, only entities that satisfy the eligibility criteria can be identified as affiliated entities.</p> <p>On the other hand, subcontracting a third entity is possible, provided the conditions stipulated in section 6.6 of the call for proposal document are satisfied.</p> <p>Interested applicants are reminded, that the beneficiary however remains solely responsible for the implementation of the action.</p>
8.	<p>Taking into account the eligibility criteria stated in the call of proposals and the grant agreement, please clarify if it is possible to indicate a non-EU University or NCA as an affiliated entity or subcontractor.</p> <p>Or else, are non-EU entities only considered as ultimate beneficiaries of the project?</p> <p>Additionally, can a non-EU entity be included as a collaborator, and if so, should this be indicated in the preliminary phase or can it be added later on?</p>	<p>Regarding the first part of the question, please refer to question 7 above.</p> <p>Regarding the second part of the question, beneficiaries under the terminology of this call, should be considered the entity(-ies) (legal and/or natural persons) that will be awarded the grant agreement. Non-EU entities can be involved to an application (see question 7 above).</p> <p>Regarding the third part of the question, please refer to section 6 of the call for proposals document “Roles and tasks of the applicant(s)”, which lists in detail the entities that can be involved to application and under which form. At the stage of submitting a proposal, the interested applicants shall include all entities that will contribute to the proposal. Should there be a need for a subcontractor in the course of the grant implementation, then the conditions set out in article II.11 of the draft grant agreement apply (Annexes Va-Vb to the call for proposals document).</p>
9.	<p>Is there a specific form for submitting the technical proposal, and are there any additional annexes required beyond Annex II (Declaration of Honor) and Annex IV (Financial Statement)?</p>	<p>Please refer to the technical specifications of the call for proposals, in particular section 16. “Submission of proposal”. The following annexes are required to be submitted:</p> <p>Annex I: Administrative data for grant application</p> <p>Annex II: Vendor identification form</p>

No.	Question	Answer
		<p>Annex III: Declaration on honour on the exclusion criteria</p> <p>Annex IV: Technical proposal covering award criteria</p> <p>The latter, Annex IV, is the form that can be used for submitting the technical proposal.</p>
10.	<p>In the context of the call for the support of the AMA, the applicant is interested in supporting the capacity building for the area of Quality, non-clinical and clinical aspects of the assessment of medicinal products.</p> <p>[Entity name x] assessors for quality, safety, efficacy and some Pharmacovigilance issues are internal staff of the Agency and also members of the Medicines Evaluation Committee (CAM).</p> <p>For the assessment of Quality, Safety Efficacy and some Pharmacovigilance issues, [Entity name x] makes use of this scientific body composed by internal and external experts, named Medicines Evaluation Committee (CAM). The external experts are nominated by the Ministry of Health according to their expertise, including most of the specialised scientific areas (clinical, non-clinical areas, quality and biotech, etc). Designated members from this Committee (both internal and external) participate at the level of European Working Parties and Committees representing [Entity name x].</p> <p>In order to have the participation of these external experts as trainers in the projected activities for the AMA call, we would like to ask EMA how we can consider their involvement.</p>	<p>Please refer to section 6 of the call for proposals document "Roles and tasks of the applicant(s)", which lists in detail the entities that can be involved to the application and under which form.</p> <p>Considering the description, the interested applicant may consider assessing whether the [Entity name x], can play the role of a co-applicant, or affiliated entity. Kindly be reminded that under these circumstances, the entity must comply with the eligibility and exclusion criteria, including submit the same forms.</p> <p>Please note that EMA will be able to perform its official assessment of the involved entities to an application only at the stage of evaluation. At this point, EMA can only provide an assessment according to the information provided. Hence, the applicants are highly encouraged to provide full information of each involved entity to the application.</p>
11.	<p>If an interested applicant chooses multiple scenarios, should each scenario have its own project plan or can one incorporate all scenarios in one project plan per call?</p>	<p>The proposed activities must be implemented based on one or more of the scenarios presented under section 3.3.1 of the call for proposals document. 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. No separate project plan is required per scenario.</p>

No.	Question	Answer
12.	<p>We are wondering how Scenario II described in the call for proposal will work in practice. As we understand it, Scenario II covers costs incurred by African NRA's (for instance Travel within Africa (5 regional participants from African NRAs required)).</p> <p>How is the reimbursement of these costs envisioned and do the African NRAs need to be part of the application?</p> <p>According to the call for proposal there is the possibility to involve both co-applicants and affiliated entities. They do, however, need to fulfil the eligibility criteria (i.e being a 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). Our understanding of this criteria is that African NRA's do not fulfil it.</p> <p>That leaves us with having the African NRA's involved as subcontractors, this does however come with other conditions. In particular condition 3 (the subcontract is awarded to the entity offering best value for money or the lowest price (as appropriate), avoiding conflicts of interests) is difficult to understand how it should be done in practice as it seems to imply some kind of competitive bidding process or price comparison.</p> <p>So our questions are:</p> <ol style="list-style-type: none"> 1. How is the cost reimbursement for African NRAs envisioned? 2. Does the cost reimbursement require the African NRA's to participate in the application as co-applicants, affiliated entities or subcontractors? 3. Is it possible for an African NRA to fulfil the criteria for being a co-applicant or an affiliated entity? 4. If not, how do we ensure that the conditions for subcontracting are fulfilled? (especially with regards to condition 3) 	<p>NB: It is explicitly underlined that the reply to the present question concerns the situation whereby RCORES would be the recipients of training programmes. It does not concern the situation whereby an applicant would like to involve RCORES in the development and delivery of training programmes which is addressed in the reply to question no.7.</p> <p>According to section 3.3 of the call for proposals document, <i>"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)."</i> (emphasis added).</p> <p>The above statement confirms that the interested applicants can consider proposing a scenario identified in section 3.3.1 of the call for proposals document, by involving African NRAs or RCORES. For example, scenario 2 "(...) Travel within Africa (5 regional participants from African NRAs required)". In such case, as "African NRAs" one can consider instead "RCOREs". In this scenario, an African NRA (or RCORES) does not fall under the definition of an affiliated entity or subcontractor because the activity under this call is to <i>"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)."</i>. Hence, those identified entities will benefit from the development & delivery of the training programs.</p> <p>Therefore, regarding question 1: It is up to the applicant to determine the reimbursement modalities to the African NRAs (or RCORES) that benefit from the training (e.g. scenario II). EMA will not request any invoices and EMA does not impose any specific modalities.</p>

No.	Question	Answer
		<p>Regarding questions 2, 3 and 4: Representatives of African NRA's (or RCOREs) joining a regional training in Africa under scenario II (section 3.3.1 of the call for proposals document) as participants that benefit from the objective of this grant should not be considered as co-applicants or subcontractors under the call.</p> <p>On the other hand, if an interested applicant wishes to engage an RCORE or African NRAs to deliver a service or supply to the beneficiary necessary for the grant, then please refer answer 7 above. However, please be reminded that "<i>Subcontracting refers to contracts concluded for the externalisation of specific tasks or activities which do not form a core part of the proposed action.</i>" (emphasis added).</p>
13.	<p>On scenario III, 5 participants from African NRAs are required. On scenario IIIa, it adds 5 additional participants. Can these participants all be from the same NRA? In summary, can we have 10 participants (total) from the same NRA for scenario III/IIIa?</p>	<p>The inclusion of participants under scenario III and IIIa does not require regional diversity. The 5 participants from Africa, or multiples thereof in case of duplication of scenarios, can come from the same NRA.</p>
14.	<p>Regarding the project plan, we are taking a lifecycle approach to the training. For this, can we write one project plan including all the areas we will be focusing on or does each area have to have its own project plan?</p>	<p>It is confirmed that <u>one</u> project plan should be submitted covering multiple training areas at once – no separate project plans are required per focus area.</p>
15.	<p>In the section 3.4 Deliverables, you state the following: "A definitive project plan (maximum 10 pages) based on the project plan submitted as part of the grant application". Could you please explain this further. We have to submit a project plan (Annex IV) and once the grant is approved, we must submit another definitive project plan? Is that correct? If so, what are the differences between the two?</p>	<p>The application to the call for proposals must include a project plan which will be evaluated against the qualitative award criteria under section 14 of the call for proposals. Should the application be successful, a definitive project plan, based largely on the initial project plan submitted as part of the proposal, should be submitted to EMA as deliverable. The definitive project plan will allow the successful applicants to fine-tune or reflect any changes that might</p>

No.	Question	Answer
		have occurred from the time of submitting their initial project plan to the time of signature and implementation of the grant agreement.
16.	<p>On the Annex IV, Ref. 2, you state the following: "description of the actors in the action, the proposed experts for training and/or secondment and the distribution of the tasks amongst them"</p> <p>Do we have to include the subcontractors and/or affiliated entities in this section? Or should we only include them once we write the definitive project plan once the grant has been approved?</p>	<p>The 'Appropriateness of the work organisation, planning, resources and methodology' – Annex IV, criterion 2 – is part of the qualitative award criteria under section 14 of the call for proposals. As such, the information provided by the applicants in response to this criterion (and to all other qualitative award criteria) <u>will serve to assess the quality of the proposal in relation to the objectives of the call.</u></p> <p>Regarding the specific qualitative award criterion no.2, it is confirmed that applicants are expected to elaborate on <u>all the actors</u> that will be involved in the implementation of the action, regardless of their role (i.e. main applicant(s), affiliated entities, subcontractors). It is underlined that the description should focus on demonstrating how the actors proposed and the distribution of the tasks amongst them is appropriate and will contribute towards the overall quality of the proposed action in relation to the objectives identified in the call for proposals.</p> <p>It is also recalled that any affiliated entities must be identified in Annex I to the call for proposals.</p>
17.	<p>Is there a required template for the proposal and what specific documents are needed. Could you please clarify which appendices or supplementary materials are required and if there is a particular format or template we should follow?</p>	<p>Please note that all the forms that need to be submitted by applicants are summarised under section 16 of the Call for Proposals. Specifically, the following annexes are required to be submitted:</p> <ul style="list-style-type: none"> Annex I 'Administrative data for grant application': this form must be used to identify the administrative information of the applicant (i.e. the details of the NCA submitting the proposal) and of any other entity which may be involved in the application (e.g. other NCAs or affiliated entities) Annex II 'Vendor identification form': this form must be used to indicate the bank account information of the applicants where payments would be executed, in case of award

No.	Question	Answer
		<ul style="list-style-type: none"> Annex III 'Declaration on honour on the exclusion criteria': this form must be used to declare whether the applicant (i.e. the NCA submitting the proposal) is in one of the situations of exclusion identified therein Annex IV 'Technical proposal covering award criteria': this is the form that must be used to submit the technical proposal. It is underlined that the technical proposal must address appropriately all the qualitative award criteria listed under section 14 of the Call for Proposals, demonstrating the overall quality of the proposed action in relation to the objectives identified in the call for proposals. It is explicitly recalled that any information pertaining to the proposal must be included directly into Annex IV; it is not possible for EMA to assess other documents accessed via hyperlinks or other external links. <p>You can refer also to EMA's reply to question no.9 above.</p>
18.	<p>Regarding an 'on the scene' training in Africa:</p> <p>a. Is it possible to choose to do the training both in the AMRH-designed Regional Centres of Regulatory Excellence (RCOREs) listed institutions, as well as in the existing regulatory agencies in sub-Saharan countries?</p> <p>b. If the training to be delivered will be in the English language, should we avoid choosing non-English-speaking countries?</p>	<p>a. According to section 3.3 of the Call for Proposals, the activity financed under this call consists of "<i>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).</i>" Therefore, it is indeed possible to propose trainings aimed to both RCOREs and sub-Saharan NCAs.</p> <p>b. EMA requires the submission of the exact deliverables as used during the training sessions without imposing a requirement to receive those deliverables in the English language. Therefore, if the training will be conducted in a language other than English, then the materials provided will be in that same language. Please refer also to EMA's reply to question no.9 under table 2 below.</p>

No.	Question	Answer
		It bears noting that it is up to the applicant to design an effective training intervention – including the choice of language and/or countries.
19.	<p>a. Regarding the project plan, the Call for Proposals specifies that it needs to include information on the “<i>Expected impact, including specific information on the number of participants from African regulators to be trained</i>”. How could we know this in advance? This is information that the receiving institution would have to give us. We understand that we would have to consult with the receiving institution before submitting the project. Is this correct?</p> <p>b. Regarding Annex IV to the Call for Proposals, it is stipulated that one of the elements that will be evaluated by EMA with respect to the project plan is “<i>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)</i>”. How can we know in advance what the training needs of a given agency are and that they do not overlap with other actions?</p> <p>c. Regarding Annex IV to the Call for Proposals, it is stipulated that one of the elements that will be evaluated by EMA with respect to the project plan is the “<i>expected impact and corresponding key performance indicators to measure the impact of the proposed action.</i>” Could you give us examples of key developmental indicators?</p> <p>d. Regarding Annex IV to the Call for Proposals, it is stipulated that one of the elements that will be evaluated by EMA as part of the ‘Quality Assurance’ criterion (criterion no.3) is the “<i>inclusion of risk register including assessment if risks are being mitigated/managed or tolerated</i>”. Could you explain this point a little more?</p>	<p>a. It is confirmed that the number of participants to be trained must be included as part of the project plan; please note that this number should represent a credible estimate. It is up to the applicant to determine how to arrive at this number (e.g. based on prior consultations with receiving institutions, past experience etc.).</p> <p>b. It is up to the applicant to decide what would be the best way to determine training needs of the target audience and complementarity (e.g. by consulting prior to the application with receiving institutions and/or other applicants).</p> <p>c. It is up to the applicant to formulate key performance indicators (KPIs) as part of the project proposal. Some examples of KPIs in the context of training are improvement in productivity levels after completing training programs, reduction in employee turnover rates due to increased job satisfaction and skill development, and achievement of specified learning objectives within the training programme.</p> <p>d. A risk register should display conscious thinking about potential risks of the proposed intervention by the applicant and possible ways to mitigate or tolerate these risks; e.g. key staff turnover and/or budget overruns.</p>

No.	Question	Answer
20.	<p>Regarding the payments, our agency is considering proposing several training activities covering various topics as part of the 'One Week to Africa' scenario, but each of the training activities may be implemented at different times. According to section 3.5 of the Call for Proposals: "A payment of the balance linked to the acceptance by EMA of all the deliverables listed under section 3.4 above for all the training and secondment activities foreseen in the proposed project plan". Does it mean that this last payment would be made once the final report of <u>each</u> training activity is delivered or when <u>ALL</u> the proposed activities have been completed?</p>	<p>In line with section 3.5 of the call for proposals, EMA will pay to the beneficiaries with which a grant agreement will be signed:</p> <ul style="list-style-type: none"> • A first pre-financing payment of 20% of the total grant within 30 calendar days following the entry into force of the grant agreement and acceptance by EMA of the definitive project plan • An interim payment of 40% of the total grant minus the amount of the pre-financing which needs to be cleared (i.e. payment of 20% on top of the initial payment) upon: <ul style="list-style-type: none"> ○ <u>completion of the first training or secondment activity</u> foreseen in the proposed project plan and ○ delivery all training materials used in the implementation of the executed training or secondment activity. • A payment of the balance linked to the acceptance by EMA of all the deliverables listed under section 3.4 above <u>for all the trainings and secondment activities foreseen in the proposed project plan.</u> <p>This means that EMA will make the final payment (payment of the balance) after acceptance of all deliverables <u>for all the trainings and secondment activities</u> as proposed in the project plan – i.e. after all the proposed activities have been completed and all deliverables have been accepted by EMA.</p>
21.	<p>Regarding in-country logistics: does EMA offer any support/collaboration with internal logistics in these countries or do you have information about companies that provide internal transfers or prepare meals for trainers in some countries?</p>	<p>EMA is not in a position to assist with or provide practical information on the implementation of project plans, including logistical elements such as transfers/travel and/or the provision of meals.</p>

No.	Question	Answer
22.	<p>We are in the process of finalising the project and we have a question regarding Annex IV. We are not sure how to write it. Is it possible to write it as a project in .doc manuscript using the questions you raised in Annex IV as a backbone, or do we have to answer the questions / points you raised directly in the boxes of Annex IV?</p>	<p>Please note that Annex IV 'Technical proposal covering award criteria' is the form that must be used to submit the technical proposal. It is underlined that the technical proposal must address appropriately all questions/criteria listed in Annex IV, in a way that demonstrates the overall quality of the proposed action in relation to the objectives identified in the call for proposals.</p> <p>However, please note that, as mentioned in Annex IV, it is also possible to use Annex IV to list the documents <u>that respond to the questions/criteria provided that these documents are included in your submitted proposal. It is explicitly recalled that any information pertaining to the technical proposal must be included or listed into Annex IV; it is not possible for EMA to assess other documents accessed via hyperlinks or other external links.</u></p>
23.	<p>Please confirm whether the following understanding is correct:</p> <p>(a) does the project proposal (to be submitted by 31 August 2024) have to contain the information indicated in Annex IV to Call for Proposals?</p> <p>(b) if the project proposal will be approved by EMA, do we then have to submit a second document with more detailed information (deliverable 1)?</p>	<p>(a) Yes, this is confirmed. Annex IV must include all the information related to an applicant's project proposal that will allow EMA to assess the project's quality against the qualitative award criteria listed under section 14 of the Call for Proposals. <u>This information must be submitted by 31 August 2024 as part of the grant application. Please see also EMA's reply to question no.22 above.</u></p> <p>(b) Yes, this is confirmed. Successful applicants <u>that will be proposed for award</u> will indeed have to submit a definitive project plan, based on the initial project proposal submitted as part of the grant application; the definitive project plan must contain all the information as listed under deliverable 1 (call for proposals document section 3.4). <u>The definitive project plan will have to be submitted after the signature of the grant agreement with the successful applicants; it is not required as part of the grant application. Please see also EMA's reply to question no.15 above.</u></p>
24.	<p>At what stage of the proposal should we identify the country we will work with?</p>	<p>This information must be identified already in Annex IV <u>to be submitted by 31 August 2024 as part of the grant application.</u></p>

No.	Question	Answer
		Specifically, the qualitative criterion no. 2 requires applicants to describe the actors involved in the implementation of the action; this description also comprises identification of the recipients of the training programmes (i.e. the specific NRA and/or RCORE).
25.	<p>(a) Is it permissible to propose the same project (themes, objectives, etc.) for more than one country? If so, is it sufficient to indicate in the draft proposal that we intend to implement it in countries X and Y?</p> <p>(b) Additionally, does each country count as a separate scenario/budget in this case?</p>	<p>(a) Yes, it is possible to propose the same project for more than one country (i.e. similar interventions implemented with different recipients of the training programmes). However, it is underlined that it is up to the applicant to put together the project proposal in a way that will achieve the highest overall quality in relation to the objectives identified in the call for proposals; <u>this is what EMA will evaluate against the qualitative award criteria (section 14 of the call for proposals) in order to determine which applicants will be proposed for award.</u></p> <p>(b) The answer to this question depends on the modalities of the specific scenario, as presented under section 3.3.1 of the call for proposals. For example, scenario II covers “one week training in Africa <u>with a cross-national focus</u>”; this means that this scenario covers the delivery of a training programme with participants from multiple countries and this explains why the fixed budget of this scenario is higher than the one of scenario I which covers “one week training in Africa <u>with a national focus (i.e. participants from one country)</u>”. If it is foreseen that participants from more than one country will be trained in one location, it is not necessary to count each country as a separate scenario/budget. If on the other hand multiple training locations in different countries are foreseen, more iterations of scenario I (one week training in Africa, national focus) would be required. It is underlined that, if necessary, one project proposal can include multiple (similar or different) scenarios applied to multiple countries; please refer also to EMA’s reply to question no.6 above.</p>

No.	Question	Answer
26.	Regarding the qualitative criterion no.2 (section 14 of the call for proposals and Annex IV), applicants are required to include a " <i>description of the actors in the action, the proposed experts for training and/or secondment and the distribution of the tasks amongst them</i> ". Do we need to provide specific names of trainers at this stage, or can we submit these names later on? Additionally, can the names of the trainers be changed later if needed?	With regard to the description of actors in the action, it is not necessary at this stage to provide specific names of trainers; <u>however, the applicants must indicate in the project proposal the fields of expertise that the identified trainers are expected to cover</u> . The applicant has the flexibility to decide who will provide specific trainings during the implementation of the grant agreement (in case the applicant is proposed for award), <u>however, the trainers eventually proposed must be able to cover the fields of expertise identified at the time of grant application</u> .
27.	Regarding the deliverable no.1 listed under section 3.4 of the call for proposals, we have the following questions and comments: (a) it is stated that the definitive project plan will be based on the project plan submitted as part of the grant application. How long do we have to deliver this information, after project approval? Can it be close to the planned implementation of the project? (b) It is stated that the definitive project plan must include specific information on the number of participants from African regulators to be trained. In order to know this, we would require information to be provided by the African agency of choice, as we do not know a priori their resources and the number of people they have available to receive the training.	(a) The definitive project plan will have to be submitted after the signature of the grant agreement with the successful applicants; it is not required as part of the grant application. While there is no specific deadline for the delivery of the definitive project plan, it is expected that it will be delivered prior to the start of the project implementation; <u>this is why the delivery of the definitive project plan and its acceptance by EMA is a condition to execute the pre-financing payment of 20%</u> (as explained under section 3.5 of the call for proposals). Please refer also to EMA's reply to questions no.20 and 23 above (b) This is understood. It is expected that the successful grant applicant will be in a position to know this information at the time of delivery of the definitive project plan which, as explained under point (a) above, should be close to the start of the project implementation.
28.	We have set up a training program for the area of pharmacovigilance that we want to submit. We have been in contact with different African NRAs regarding the project and have now finalised projects with two partner countries. The training projects are similar, however show certain differences as there are different needs in both countries that need to be addressed as countries are on different maturity levels. It is not possible for us to develop a common training project and therefore we want to conduct the projects with	Firstly, the EMA understands that by "separate project", you refer to the submission of separate grant applications for each of the two training programmes. Based on this understanding, please note that there is no limit to the number of grant applications (i.e. project proposals) that one NCA can submit. It is underlined however that, if necessary, one grant application (i.e. project proposal) can include multiple (similar or different) scenarios (as

No.	Question	Answer
	<p>both African NRAs separately. We plan to submit the planned program with each NRA as a separate project, though they are very similar. Could you please clarify whether it is possible for one NCA to submit several projects or can one NCA only submit one project in a specific area (e.g. in the area of pharmacovigilance)?</p>	<p>defined under section 3.3.1 of the call for proposals) applied to multiple countries.</p> <p>Regarding the specific case presented in the question, it would not be necessary to submit the proposed training interventions in different countries as separate grant applications/projects – they could also be put together as different ‘parts’ under one project plan, with multiple iterations of e.g. scenario I (one scenario for each specific country). In such case EMA will assess the one, consolidated project plan.</p> <p>It is underlined that it is up to the applicant to put together the project proposal in a way that will achieve the highest overall quality in relation to the objectives identified in the call for proposals; this is what EMA will evaluate against the qualitative award criteria (section 14 of the call for proposals) in order to determine which applicants will be proposed for award.</p> <p>Please refer also to EMA’s reply to questions no. 6 and 25 above.</p>
<p>29.</p>	<p>We were wondering if it would be possible to receive a .docx version of the pdf <i>Call for proposals - Grant procedure EMA/GRANT/2024/02/IA ‘Medicines regulatory systems strengthening in Sub-Saharan Africa’</i>. It would simplify filling out the annexes for the application as we are unable to edit the pdf file and, if we convert it to .docx format on our end, the formatting changes.</p>	<p>The following Annexes are the ones that need to be filled in by applicants:</p> <ul style="list-style-type: none"> • Annex I: Administrative data for grant application • Annex II: Vendor identification form • Annex IV: Award criteria questionnaire <p>Annex II is already published in .docx format and can be accessed here: https://www.ema.europa.eu/en/documents/template-form/annex-ii-call-proposals-vendor-financial-identification-form_en.docx</p> <p>Annexes I and IV will also be made available in .docx format.</p>
<p>30.</p>	<p>a. We would like to ask if it is obligatory to attach any other documents except for Annexes I, II, III and IV in the application process?</p>	<p>a. No, it is not obligatory to submit any other documents beyond Annexes I, II, III and IV. Please see also EMA’s reply to point (g) below.</p>

No.	Question	Answer
	<p>b. Regarding the Draft Grant Agreement (Annex V), do we need to fill out and attach this document together with the Annexes or will it be completed after the evaluation process (in case the application is successful)?</p> <p>c. Regarding the bank account, is it absolutely necessary to have it already established by the 31 of August? In case a grant will not be awarded, there is a risk of bearing the cost of running a bank account that will be unjustified.</p> <p>d. Can money on the project bank account stay there through the change of years? Some projects require that account is cleared by the end of the year, is the case for this project?</p> <p>e. The grant procedure stipulates that we must submit annexes I, II, III and IV. Is there any other document? Any other template? In other words, does an application consist only of an email sent to the given address and these 4 annexes?</p> <p>f. If a project involves 2 African partners, where should it be mentioned? Only in annex IV?</p> <p>g. Is there any template or example for the proposal itself? There are annexes very clearly described but somehow there is no base document described (the one to which annexes should be attached).</p>	<p>b. No, this does not need to be filled in by applicants. EMA will initiate the signature of grant agreement(s) with the applicants that will be proposed for award, following the conclusion of the grant procedure.</p> <p>c. Given the risk explained in the question, we confirm that it will be acceptable not to establish a bank account by the 31st August 2024; in such case, the information in Annex II ‘Vendor identification form’ can be left blank.</p> <p>d. The modalities of the bank accounts established by applicants are outside the control of EMA and advice or guidance on this element cannot be provided by EMA. As per Article I.6 of Annex V ‘Draft Grant Agreement’, the successful applicants to which a grant will be awarded will have to establish a bank account in order to receive the payments from EMA. EMA does not impose any obligation to “clear the account”.</p> <p>e. No, it is not obligatory to submit any other documents beyond Annexes I, II, III and IV. Your understanding is correct that an application must consist of sending an email to ema-grant-2024-02-ia@ema.europa.eu in which Annexes I, II, III and IV are attached. Please see also EMA’s reply to point (g) below.</p> <p>f. The information on the recipients of the training programmes (i.e. the specific NRA and/or RCOE) must be indicated only in Annex IV. IF your question refers to the possibility of involving African partners in the development and delivery of trainings (instead of them being the recipients of the training programmes), please refer to EMA’s reply to question no.7.</p> <p>g. Please see the reply to question no. 22. Annex IV ‘Technical proposal covering award criteria’ is the form that must be used to submit the technical proposal. It is underlined that the technical proposal must</p>

No.	Question	Answer
		<p>address appropriately all questions/criteria listed in Annex IV, in a way that demonstrates the overall quality of the proposed action in relation to the objectives identified in the call for proposals. However, please note that, as mentioned in Annex IV, it is also possible to use Annex IV to list the documents that respond to the questions/criteria provided that these documents are included in your submitted proposal. It is explicitly recalled that any information pertaining to the technical proposal must be included or listed into Annex IV; it is not possible for EMA to assess other documents accessed via hyperlinks or other external links.</p>

⇒ For the Q&As discussed during the [Information session](#) on 22/05/2024, please see Table 2, below.

Table 2

No.	Questions during the information session on 22/05/2024	Answer
1	<p>The implementation period is until the fourth quarter of 2027. Is there a specific start date for the project, or can it start any time after the grant agreement is signed?</p>	<p>There is no specific start date required. Applicants can propose the start date in their submission, and provided it is clearly explained in their proposal.</p> <p>In particular, the timeline for implementation should be detailed in the application, and EMA will accordingly evaluate and award based on the provided information. Typically, grants are signed immediately after the award, but if the implementation is proposed to start later, then it is possible to have the implementation period adjusted to ensure sufficient time. This flexibility allows us to fine-tune the timeline within the grant agreement, making it feasible as long as it is properly explained in your proposal.</p>
2	<p>While reading the call, it was noticed there are many beneficiaries. According to a document, I found on your website, 26 countries have deposited after the signature and ratification. Is this number still correct?</p>	<p>At the moment, 27 countries have ratified the AMA Treaty. The African Union Development Agency (AUDA-NEPAD) maintains an overview of countries which have ratified via https://amrh.nepad.org/african-medicines-agency-ama/.</p>
3	<p>To ensure the proposal is as beneficial as possible, could you clarify the current state of play in the involved countries? The call encourages a focus on</p>	<p>Regarding the current state of play and the list of countries that have ratified the AMA Treaty, EMA refers to the overview as maintained by the African</p>

No.	Questions during the information session on 22/05/2024	Answer
	<p>pharmaceutical quality and GMP inspectors. Are these the crucial topics for the AMA?</p>	<p>Union Development Agency (AUDA-NEPAD) via https://amrh.nepad.org/african-medicines-agency-ama/. However, this information is not an exclusionary criterion for any training activities you might be developing with your counterparts in Sub-Saharan Africa. Furthermore, it is for the interested applicant to consider the current state-of-play depending on the interested counterpart(s) in Sub-Saharan Africa.</p> <p>In terms of specific areas of intervention, pharmaceutical quality and GMP inspectors are indeed encouraged because, by means of this grant, EMA aims to develop specific training curricula in these areas on a continental basis. However, this does not mean that these areas will be preferred in the evaluation of proposals. Any areas listed under point (2) of section 3.2 of the call for proposals, and as mentioned in the slides, can be considered and provided they meet the eligibility criteria.</p> <p>Therefore, there is no requirement to focus exclusively on the encouraged topics as long as your proposal falls within the specified areas.</p>
4	<p>Should we specify a particular country in our proposal, or is there a different process for determining the country for activities such as an 11-week training in Africa? How will the decision be made regarding which country will be the focus?</p>	<p>It is expected that you will define which National Regulatory Authority (NRA) or counterpart you will be working with in your proposal. This could be a single NRA or country, but we also welcome proposals with a regional focus that include colleagues from several NRAs across the continent. Ultimately, the decision is for the interested applicant to identify the relevant NRAs or countries in its proposal.</p>
5	<p>With regards to subcontracting; if we book airplane tickets via a travel agency, does this count as subcontracting? Additionally, if our national administrative law requires us to use a travel agency for booking should this standard procedure be considered subcontracting?</p>	<p>No, in this case it is not necessary to consider this as subcontracting.</p>

No.	Questions during the information session on 22/05/2024	Answer
6	I'm interested in the approach you mentioned for visual training. Do you envision that we provide a budget for this activity to fit the selection criteria, or can this be done as an in-kind collaboration without any budgeting?	<p>To clarify this question: the interested applicants asks if a day of virtual training can be provided as an in-kind contribution without any associated budget.</p> <p>If an interested applicant intends to provide the training as an in-kind contribution, then this must explicitly be stated in the proposal. Furthermore, yes, it is possible to offer a day of virtual training as an in-kind contribution. However, if the proposal mentions a day of virtual training, then EMA will assume that the applicant is requesting a budget for this activity and will include it in the calculation of the grant amount, if the respective proposal is successful.</p>
7	Regarding subcontracting, we also have a travel agent whose services we use. From what has been said, we understand that we can use their services without classifying them as a subcontractor. Is that correct?	Yes, this is correct.
8	What procedure should we follow to inform you about who we are subcontracting?	<p>If an interested applicant needs to subcontract certain activities, particularly for administrative elements or specific trainings, he must identify and detail all related information in the proposal. In particular, clearly state which activities will be subcontracted and describe the nature of these subcontracted activities.</p> <p>During the evaluation, EMA may ask additional requests for clarifications about these aspects to ensure everything is clear and compliant. Interested applicants are reminded, that subcontracting details do not impact the quality assessment of a submitted proposal, and clarifications can be provided if needed and required by EMA.</p> <p>Additionally, be aware that subcontractors must adhere to certain obligations outlined in the draft grant agreement (Annex V to Call for Proposals), such as</p>

No.	Questions during the information session on 22/05/2024	Answer
		confidentiality requirements. These standard obligations will apply to all subcontractors involved in the project.
9	I have a question regarding the training materials required for payments. In what language should we provide these materials? Specifically, if we deliver training in Portuguese for Portuguese-speaking countries, will we need to translate the training materials into another language?	<p>EMA requires the submission of the exact deliverables as used during the training sessions. Therefore, if the training is conducted in Portuguese, then the materials provided will be in Portuguese as well.</p> <p>Please note, that while it is strongly preferred that the submitted proposal to the EMA is drafted in English language, translating the training materials is not a requirement.</p>
10	How do we manage budget adjustments given the fixed amounts specified in the call, especially considering the potential changes in travel costs over a long implementation period? Is it possible to fine-tune the training plan if costs change, particularly for activities like training in Africa?	<p>There is no mechanism available to adjust the fixed amounts as already specified in the call. The amounts defined in the call have been carefully calculated to account for various factors, including potential inflation. This estimation is based on available information and previous contracts or activities from EMA side.</p> <p>Interested applicants are reminded, that if one finds the allocated budget for certain activities, like training in Africa, overestimated, the beneficiary will still receive the full allocated amount and he can redistribute it as needed. This is the offered flexibility to manage budget variations in the course of the grant agreement.</p>
11	Did you calculate the daily allowance in the budget according to the current allowances, considering that daily allowances may vary at the national level?	The daily allowance is based on the rules applicable for the EMA.
12	Do you have any information regarding the reliance practices mentioned in the objectives (3.2) of the call? What specifically do these practices entail? Additionally, do you have insights into what the agencies might require in this particular area?	<p>Reliance is understood as the act whereby the national regulatory authority (NRA) in one jurisdiction may take into account and give significant weight to assessments performed by another NRA or trusted institution, or to any other authoritative information in reaching its own decision. An activity fostering to this practice will be understood as contributing to the grant's objective.</p> <p>EMA does not have insight into the specific reliance needs from National Regulatory Authorities (NRAs). Establishing reliance practices, particularly</p>

No.	Questions during the information session on 22/05/2024	Answer
		<p>tailored to the specific agency's needs, would likely be a collaborative effort between the applicant and the relevant NRA you are partnering with.</p> <p>Please also refer to Table 1, question 4 for further information.</p>
13	<p>Have the countries been informed about the launch of the call and the commencement of this procedure? Should we take the initiative to contact them directly to discuss the current status, or has communication been formally conveyed to them?</p>	<p>EMA has not reached out to individual countries or organisations regarding the launch of the call for proposals.</p> <p>It would be the responsibility of the interested applicant to communicate with their partner(s) directly.</p> <p>EMA has ensured that the call for proposals is published on the EMA's website and shared the information with its general partner in Africa, AMRH. Additionally, Alternate Path is also aware of the goal.</p>
14	<p>Could you please provide the link to where the Q&A document will be located, along with this presentation? This will ensure we know where to find the information accurately.</p>	<p>The Q&A document of the presentation, is table 2, to this link: https://www.ema.europa.eu/en/documents/other/questions-answers-relating-grant-procedure-no-ema-grant-2024-02-ia-medicines-regulatory-systems-strengthening-sub-saharan-africa_en.pdf.</p> <p>And the presentation document is available in this link: https://www.ema.europa.eu/en/documents/presentation/eu-4-ama-leveraging-european-expertise-medicines-regulation-africa_en.pdf.</p>
15	<p>Who would be responsible for organising the networking event, particularly if we were to conduct training in Africa? Additionally, is there a preferred methodology, such as agile methodology, that would potentially earn us more points in the project plan?</p>	<p>Regarding the networking event, it has been factored into the fixed budgets and pre-defined scenarios. However, organising one, is not mandatory as part of the scenario.</p> <p>EMA has allocated funds for it because it is considered as a logical event in certain scenarios, like hosting a networking event alongside training in Africa. However, excluding such an event would not make the activity ineligible.</p> <p>Responsibility for the event lies with the applicant and should be determined through dialogue. Regarding the project plan methodology, EMA identifies no</p>

No.	Questions during the information session on 22/05/2024	Answer
		specific preference beyond what is outlined in the call for proposals. In any event, interested applicants must describe the rationale of the chosen methodology to be applied to achieve the objectives of the call.