EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HADEA)

Health and Food
EU4Health

Brussels, 19 July 2022

Questions and Answers related to the
Call for proposals under the Annual Work Programme 2021
Action Grant to support a HERA laboratory network (EU4H-2021-PJ4)

Policy questions

1. **Could you please provide more information on the laboratory networks that already exist?**

The call document reads: "*activities will be defined and carried out taking into account of the EU reference laboratories to be established under Article 15 of the Proposal for a Regulation of the European Parliament and of the Council on serious cross border health threats, and in close collaboration with ECDC, in particular its activities under Article 5 (surveillance network), Article 8 (early warning and response system) and 10 (identification of emerging health threats) of Regulation (EC) No 851/2004 (ECDC Regulation), and the planned future network of EU reference laboratories and activities under other relevant EU policy areas (e.g. One Health) to ensure complementarities and avoid overlap and duplication*".

ECDC surveillance network include surveillance and laboratory networks working on specific diseases, mainly on EU territory. More information can be found here: https://www.ecdc.europa.eu/en/about-us/what-we-do/partners-and-networks/disease-and-laboratory-networks

2. **Will the network be based on or include the EVD Labnet too?**

The EVD Labnet is one of the networks operated by the ECDC. As written under question 1, applicants should clarify their collaboration with these networks.

3. **As laboratory networks already exist, what gaps do you expect to be covered by this call?**

The gaps identified during the COVID-19 crisis that should be better addressed through this call are the following:

- Early detection and warning on emerging health threats, notably from outside the Union;
- Fragmented involvement in global surveillance, and access to surveillance results and relevant biological samples from third countries;

- Paucity and lack of comparability of scientific data;
- Translation of scientific data (e.g. biological characterisation) into operational recommendations on medical countermeasures for prevention and treatment.

Proposals can also indicate additional gaps the network could address that you may have identified and are not mentioned in the call.

4. What is the link between this action and Joint Actions EMERGE and SHARP of the Third Health Programme?

EMERGE is a joint action focused on cooperation and support inside the network EMERGE and the coordination of activities with other relevant networks. EMERGE JA is over now and has been followed by the SHARP JA. As any other joint action, it is directed to support directly Member States in this case by increasing laboratory capacity at EU level including training and quality assurance.

The HERA laboratory network will have a global oriented approach, while EMERGE and SHARP focus on the EU territory.

A rapidly reacting HERA laboratory network is expected to further reinforce the current structures for a swift response on potential health threats with high impact potential.

5. Who should we contact from the HERA board and the ECDC for the inclusion of both in the call application?

Please note that it will be HERA and not the HERA board who is expected to be part of the governance of the HERA laboratory network. HERA will consult the HERA board when needed. This is also applicable to the ECDC. In addition, at this stage of the process there is no need to indicate specific names in the organisations, the inclusion of HERA and ECDC is enough.

6. How can proposals aim to develop sustainability after four years?

Proposals should consider the long-term impacts of the action. As indicated in the call document: "*Developing a blueprint concerning the sustainable establishment of the network and achievement of long-term impacts described in the annual work planned after the end of the project, including tangible non-high level policy recommendations. These should include reflections on the need for scope extension (geographical and pathogens prioritisation) and options for potential institutionalisation of the HERA laboratory network, to be delivered at least 6 months ahead of the end of the final reporting period of the project duration*".

7. How can we address countries' data sharing legal restrictions? How can we develop an IT network without a secretariat or data centre, or are we to use the IT HERA

platform? Would we be offered a mandate for data collection, like the one of the ECDC?

Please include the challenge of data sharing legal restrictions in your proposal and indicate how you expect to address it. We expect laboratory networks to propose an IT solution for data and results sharing. This solution should be connected to the HERA IT platform that is currently under development, as well as to the ECDC data collection system.

8. Should the proposal clearly explain how data security will be ensured or should this point be developed during the project lifetime?

While this aspect should be developed during the project lifetime, proposals ought to include some indications on how you plan to achieve this.

9. Who is developing the HERA IT Platform since the call SANTE/2021/OP/0009 dedicated HERA Preparatory Action: Horizontal — Intelligence Gathering, Threat Assessment and Global Surveillance was cancelled?

Some parts of this action will be addressed internally, while others will be subject to an open procedure. Please refer to the Annual Work Programme 2022, which reads under Procurement the action *CP-P-22-01.03 IT development for early warning, modelling, simulation, and forecasting (HERA)*. The call for tender is currently under preparation.

10. Will the network need to include highest-confinement (BSL4) capacities?

This aspect is not specifically requested in the call document. However, the action should seek to address any emerging pathogens of concern for public health, and therefore it is probable highest-confinement capacities will be included.

11. Are countries that do not allow the exportation of human samples to be directly excluded?

No, countries that do not allow the exportation of human samples can be included in the proposals. While some partners within a consortium may cover sample exportation, others may focus on data sharing.

12. Does a similar call exist for chemical risks instead of pathogens?

Currently, we only have this call, which focuses on pathogens, but the organization of other calls addressing other type of threats, including chemical threats, might be reconsidered further on.

<u>Administrative questions</u>

13. What information does the additional document have to contain, and is this document included in the maximum number of pages?

Indeed, there is a limit of 70 pages for proposals (part B). Evaluators will not consider any additional pages. Annexes must be uploaded at the submission stage to provide info (e.g. CVs (free format) of core project team and list of previous projects). All the documents to be uploaded are listed in the Portal. You may be asked at a later stage for further documents (for legal entity validation, financial capacity check, bank account validation, etc).

14. Who can we contact in case of questions following this information session?

Please address any communication you may have to the functional mailbox HaDEA-HP-CALLS@ec.europa.eu.

15. Do you expect participation of laboratories outside Europe?

The project should allow the widest possible geographical coverage at EU level and global level. For this purpose, at least one of the laboratories/research institutes should have e.g. branches or associated members to allow the network to have widespread global coverage ideally in all continents. The consortium should consist of top-internationally leading laboratories or research institutes. Laboratories outside Europe could participate if compliant with the eligibility criteria set in the call document.

16. Is a partner from Ukraine eligible for funding?

The proposals for an action under the EU4Health Programme must relate to activities taking place in "eligible countries". Currently only the EU Members States, Iceland and Norway are eligible for funding. However, in July 2022, the EC signed with Ukraine a EU4Health Association agreement with retroactivity from 01 January 2022.

17. Is the UK eligible for funding?

The proposals for an action under the EU4Health Programme must relate to activities taking place in "eligible countries". Currently only the EU Members States, Iceland and Norway are eligible for funding.
UK is not amongst the eligible countries under the EU4Health Regulation. Therefore, entities based in the UK are not eligible as beneficiary for funding under this Regulation and this specific call.

18. Could you please define affiliated entities? Can the affiliated entities outside of the EU receive part of the funding through the beneficiary?

An entity can be considered affiliated (AE) to a beneficiary if it fulfils the following conditions:

a) Complies with the eligibility and non-exclusion criteria applying to applicants, specifically, does not fall within one of the situations referred to in Articles 136(1) and 141(1) of the Financial Regulation.
b) Has a structural link with a beneficiary, in particular a legal or capital link.
c) The structural link is neither limited to the action nor established for the sole purpose of its implementation. This means that the link would exist independently of the award of the grant; it should exist before the call for proposals and remain valid after the end of the action.

AE, just like the beneficiaries, must register in the Participant Register and be validated, unless already provided with a validated participant identification code (PIC).

AE will get a part of the grant money and must therefore comply with all the call conditions and be validated (just like beneficiaries); but they do not count towards the minimum eligibility criteria for consortium composition (if any). Affiliated entities do not sign the grant agreement. They are asked to sign a declaration of honour.

For more information on AE, please check the relevant section(s) of the EU4Health Model Grant Agreement and the Annotated Grant Agreement.

19. Are SMEs eligible as subcontractors?

Yes, SMEs are eligible as subcontractors, in accordance with the rules of their home country.

20. Could you please confirm what type of organisations can apply to this call? Can only laboratories apply or also research centres or independent experts in infectious diseases?

Applicants must be public or non-profit, or profit private laboratories or research institutes.

21. Would it be possible to extend the application deadline?

The timeline to sign the grant agreement is very tight (by the end of 2022) and we cannot extend the deadline.

22. The template includes a section called "Experts (if applicable)" with the comment "*Explain if national and/or international experts will be nominated by national authorities to support the project implementation*". Does this section apply to this call?

No, this section does not apply to this call and does not have to be included.
Please note you can also contact your National Focal Point (NFP) for more information. The NFPs are the national experts for the Health Programme in EU countries and participating

countries. NFP representatives are appointed by their national health ministries. Please find more information on National Focal Points (europa.eu).

23. Can laboratories be part of the proposals of different consortia?

This is up to you, we expect to sign one grant agreement. Please note that to present a good proposal you have to be fully involved in its preparation.

Financial questions

24. Does the reimbursement rate of 60/80% apply to all activities, including project coordination, or is coordination funded at 100%?

The same reimbursement rate applies to the total of eligible costs of the proposal.
Please note that, according to Article 8(3) of the EU4Health Programme and the Call document, actions with a clear Union added value shall be considered to have exceptional utility, inter alia, where:

- *At least 30 % of the budget of the proposed action is allocated to Member States whose GNI per inhabitant is less than 90 % of the Union average; or*
- *Bodies from at least 14 participating Member States participate in the action, of which at least four are Member States whose GNI per inhabitant is less than 90 % of the Union average.*

In cases of exceptional utility, the contribution by the Union may be up to 80% of eligible costs.
The list of EU countries and their GNI is available at the following link. As soon as an updated version will be available, it will be published on our website.

25. Is subcontracting supported at 100% or 60%?

Subcontracting costs would be reimbursed by EU at normally 60% (or 80% in case of exceptional utility). Those procurement (subcontracting) rules foresees that the beneficiary (not the EU) buys a service at the condition to fully pay (100%) for it.

26. Is there any type of restriction on who/what type of organisations is co-financing to complete the EU funding?

There is no specific restriction on what type of entities can co-finance actions under the EU4Health Programme.
If the reimbursement rate of the grant is 60%, the beneficiary must fund the remaining 40% from other sources in line with the co-financing principle. The co-financing principle means that the part of the costs that is not reimbursed by the grant has to be covered by the forms of co-financing listed in Article 190 of the FR (i.e. beneficiary's own resources, income generated by the action or work programme or financial or in-kind contributions from third parties.)
Additionally, article 9.2. of the Model Grant Agreement stipulates that: "*Other third parties may give in-kind contribution to the action (i.e. personnel, equipment, other goods,*

works and services, etc. which are free-of-charge), if necessary for the implementation. Third parties giving in-kind contributions do not implement any action tasks. They may not charge costs or contributions to the action and the costs for the in-kind contribution are not eligible. The third parties and their in-kind contribution should be set out in Annex I". This means that in-kind contributions are allowed, but they cannot be declared as cost – which is also confirmed by Article 6.3 of the Model Grant Agreement.

27. The last part of the budget file (sheet detailed budget) concerns the income of the beneficiary and the contribution of third parties: should this part be filled in as proof of the 20/40% co-financing?

In the detailed budget template you need to clearly indicate any potential monetary contribution from third parties. If this is not the case and 20/40% co-financing is your own contribution, you should just mark the requested EU contribution under the income section and the rest is automatically taken as an own contribution on Excel.

28. Our employees salaries are eligible contribution?

Yes, employees' salaries are an eligible contribution, and thus can be covered at 60/80% and the rest is considered as your own contribution.

29. Would office rental cost count as an eligible cost?

No, this is generally not eligible and is covered by the overheads, unless it is a very specific rental which is needed only for this action.

30. Is the audit certificate also necessary for public entities?

Certificates on the financial statements (CFS) are necessary also for public entities. In the case of public entities, CFS can be provided by their internal audit service or independent financial officer.
On the other hand, at the application stage, the financial viability assessment is not mandatory for public entities.

31. For this call, will an end-of-project audit be required for a beneficiary with funding above EUR 430 000? If so, is this an eligible expense?

Yes, the Model Grant Agreement indicates that Certificates on the financial statements (CFS) are required for requested EU contribution to costs above EUR 325 000. If required, the cost of the audit is eligible.

32. Is there a different application form for consortium, or it is the same as for individual applicant?

The application form is the same for all applicants.