Consultation on the Strategic Research and Innovation Agenda of the European Partnership on One Health Antimicrobial Resistance

31 March – 28 April 2023



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Background

In response to the urgent threat of antimicrobial resistance, the European Partnership on One Health Antimicrobial Resistance (EUP OH AMR) is one of the key European partnerships that has been identified within the framework of the Horizon Europe Research and Innovation (R&I) programme¹ to contribute to the objectives of the EU One Health Action Plan against AMR² and to the recent European Commission (EC) proposal for a "Council Recommendation on Stepping up EU actions to combat antimicrobial resistance in a One Health approach" ³. Both documents state the importance of research and innovation for the development, evaluation and implementation of measures against AMR. The EUP OH AMR is foreseen to start 2025 and will deploy a research and innovation (R&I) programme, co-funded by the EC and the EUP OH AMR partners. In order to prepare for the EUP OH AMR, the EC has granted a coordination and support action (CSA), DESIGN OH AMR, lasting from 1 May 2022 to 30 April 2024.

The Strategic Research and Innovation Agenda and the consultations performed to complete the first draft

One of the tasks of the DESIGN OH AMR is to compose a Strategic Research and Innovation Agenda (SRIA), which will guide the activities of the EUP OH AMR. An important element of the SRIA is the Research and Innovation Objectives⁴, which was developed through a number of consultations with the scientific community and stakeholders during 2022. The SRIA is a broader document, containing also the overall objectives, the planned activities and funding instruments, the interaction with other partnerships and initiatives and the monitoring and evaluation. A preliminary draft of the SRIA and an invitation to complete a survey, was sent to country representatives that have expressed interest to join the EUP OH AMR as well as members of the JPIAMR management board and partners of the JPIAMR-ACTION ERA-NET. In order to attract further members, the invitation was also sent to National Contact Points (NCPs) of all additional EU member states and countries associated to Horizon Europe. Finally, the SRIA and the survey invitation were also sent to a number of key stakeholders.

The survey was open from 31 March – 28 April 2023. In addition, a workshop was held on 20 April with country representatives. After the survey was closed, the SRIA was updated, taking the comments of the survey into consideration. Some comments will be more relevant for the subsequent step of the preparation of the EUP OH AMR, when the foreseen activities will be planned in more detail. The updated first draft of the SRIA was published on 22 May 2023⁵.

This report highlights the statistics of the survey results, as well as a summary of the received comments. Please acknowledge this report as a summary of the most frequent and important comments but that all received comments have been considered in the revised version of the SRIA.

¹ Horizon Europe Work Programme 2023-2024, Health

² EU One Health Action Plan against AMR (2017).

³ European Commission proposal for Council Recommendation on AMR (26 April 2023)

⁴ The R&I objectives of the EUP OH AMR (22 may 2023)

⁵ First draft of the SRIA of the EUP OH AMR (22 May 2023)

Demographic distribution of the survey responders

The invitation was sent to 157 country representatives (mainly funding agencies, ministries and NCPs) as well as 39 key stakeholders (EU agencies and EC directorates, other relevant European partnerships and funding initiatives, WHO, OECD, the AMR stakeholder network et c.). Responders were asked to respond as representatives for their organisation or as a collected answer from their country. The survey was open from 31 March – 28 April 2023. In total 42 replies were received. In addition, the EC directorates general and the EU agencies (DG-RTD, DG-HERA, DG-SANTE, DG-AGRI, EMA, ECDC and EFSA) provided one collective answer, sent by e-mail.

Type of organisation that is submitting feedback

Table 1 shows the distribution of type of organisations that the responders represented. The majority (54 %) of the answers were received from funding agencies.

Type of organisation that is submitting feedback	Number of responses
Funding agency	23 (54,8%)
Ministry	5 (11,9%)
International organisation	2 (4,8%)
EU/EC directorate/agency	1 (2,4%)
NGO/association/foundation	3 (7,1%)
Other European partnership	4 (9,5%)
Other	4 (9,5%)
Total	48 (114,3%)*

Table 1. Distribution of type of organisation submitting feedback.

*It was possible to give several answers.

Geographical distribution

The geographical distribution of the organisations submitting feedback is shown in Figure 1. Replies were submitted from 24 different countries. 81 % of the replies were received from EU countries. 3 replies were received from countries associated to Horizon Europe (Armenia, Georgia and Moldova). In addition, representatives from Canada, South Korea, Switzerland and United Kingdom replied to the survey. In most cases where several answers were received from the same country, this reflected European or international organisations based in these countries.



Figure 1. Geographical distribution of the organisations submitting feedback.

Replies to the survey

For each section of the SRIA, the survey included an initial yes or no question regarding the appropriateness of the content. This was followed by free-text questions on suggestions of additions and alternatives and general comments.

Some comments have also been dealt with under other section than where they were originally inserted.

Introduction and challenges

Are the problem description/challenges adequately described in the Introduction and challenges chapter?

36 responders (85,7%) replied Yes to the question on whether the problem description/challenges adequately described.

If No, please specify any broad challenges that are missing or unclear?

Free-text answers included that wild-life, companion animals, plants/crops, food systems and the environment need to be further described. The problem with supply security with currently effective medicines should also be mentioned.

Do you have any additional comments on the Introduction and challenges section?

Apart from issues mentioned above and some factual mistakes/typos/references that have been corrected, responders suggested to include/further emphasise:

- the role and support of the industry
- migration from regions with loose handling of antibiotics
- the impact on overall health care resources
- further highlight the importance of preventative measures
- vaccines
- antiparasites and -fungals
- climate change
- detection, also of AMR in non-pathogenic bacteria
- implementation in One Health sectors in different countries
- companion animals and wildlife
- targeting collaboration efforts to geographical hot spots
- support of ERA and widening participation
- other socioeconomic parameters, apart from overuse and inappropriate use
- gender

In addition, there was a concern that the restriction to the impact on human health is not in line with a One Health approach, that the boundaries to EUP AH&W need to be better clarified and that the environmental aspects need to be strengthened. The boundaries to JAMRAI-2 as well as the meaning of "coordination" and "alignment" also needs to be better clarified.

Partnership objectives and intervention logic

Do the general, specific and operational objectives address the overall ambition of the partnership?

31 responders (75,6 %) replied Yes to the question on whether the general, specific and operational objectives address the overall ambition of the partnership.

If No, please suggest alternative general, specific and operational objectives

The survey had three different questions on the different levels of objectives but the comments have here been merged since they are often interconnected.

General comments:

- more weight to industrial research, break barriers between academia and industry, companies engaged already as partners of projects
- lack of benchmarking and feedback tools
- overlap of the certain objectives, e.g. General Objective (GO)1, Specific Objective (SO)1 and Operational Objective (OO)1
- unclear link between GOs and Impact
- personalised medicine not included
- include interaction with medicine regulators
- include patient engagement
- activities and tools to specifically support the innovation and implementation of research achievements
- clarify which areas that will be covered by EUP AH&W
- SO3 needs to be better reflected in the OOs
- build on what is already known, gap analysis
- knowledge transfer towards widening and Low- and Middle-Income Countries (LMICs)

Suggestions of alternative general objectives:

- GO2. Enhanced scientific evidence-based support for policy measures and practices to prevent, detect, control, and treat drug resistant infections
- G01: establish governance and funding for the stakeholders across OH structures. GO2: solutions for unmet medical and non-medical needs of human & animals, food security, trade. GO3: innovation by establish OH platforms for private and public programs, regulatory, academics, and civil society

Suggestions of alternative specific objectives:

- SO2: Include also innovative solutions for keeping older antibiotics on the European market, pull incentives et c
- SO2: Include integrating AMR surveillance into broader genomic surveillance systems
- SO3: Include set-up of start-up/ new companies
- SO3: Feedback to policy need to be further defined

• the 3 aims Understand, Prevent and Tackle would probably fit well as specific objectives of the partnership.

Suggestions of alternative operational objectives:

- interdisciplinarity, One Health and international OOs should be overarching all OOs
- unbalanced OOs, OO3 to heavy, consider splitting
- distinguish what is specific for AMR or more general, for example in the regulatory landscape
- OO2: include the gender lens

Are the proposed actions sufficient for addressing the operational objectives?

35 responders (83,3%) replied Yes to the question on whether the proposed actions are sufficient for addressing the operational objectives.

Comments on Actions:

- actions need to be further specified, for example regarding "strengthening of dialogue", collaboration activities, mobility measures, OO3 actions...
- OO2, Action 2: Consider distinguishing LMICs and widening countries
- OO2, Action 3: Take IP rights into consideration for data sharing
- include tools for a proper design of prevention and surveillance programs
- include governance mechanisms and platforms for cross sectoral and cross disciplinary collaborations and knowledge exchange
- establish coordination mechanisms for organisations and initiatives that fund research on development of therapeutics and vaccines at different levels (both for humans and animals), including regulatory agencies
- include activities that will enhance the leadership of Europe in the domain of health/ pharmaceuticals

Are the proposed indicators suitable for proper monitoring of the operational objectives of the partnership?

33 responders (80,5%) replied Yes to the question on whether the proposed indicators are suitable for proper monitoring of the operational objectives of the partnership

General comments on indicators:

- specify the indicators further, including target numbers
- how do you measure alignment?
- Continuous cross-sectoral impacts, outputs and outcomes indicators are needed
- Add indicators for actions concerning cross-cutting issues

Suggestions on alternative impact indicators

 Increased prominence of OH and AMR related research, incl products, partnerships and publications

Suggestions on alternative outcome indicators

- share of specific projects that end up in usable products
- number of innovations that reached the market
- SO2: add also outcomes from thematic pillars other than Therapeutics and Diagnostics
- add number of identified antimicrobial targets
- number of policy-driven meetings in which OH AMR members participate

Suggestions on alternative output indicators

- number of early career researchers that were competitive for funding after OH AMR funding ended
- include also qualitative indicators
- include indicators for two-way dialogue
- number of projects that re-use existing data and include data in a proper repository
- number of projects which includes social sciences, SME/Industry, with an increased level of TRL
- number of policy documents, policy guidelines, recommendations, strategic roadmaps
- number of planned clinical trials for novel antimicrobial substances
- number of female researchers and females leading and/or coordinating research projects
- indicators for 1) the commitment and investment, 2) the synergies created, and 3) the alignment of priorities

Research & Innovation Objectives

Do you consider that the 3 aims (Understand, Prevent and Tackle) are appropriate?

37 responders (90,2%) replied Yes to the question whether the 3 aims are appropriate.

Comments on the 3 aims

- Innovation and implementation, as well as participation of industries need to be further emphasised
- Narrow definition of One Health
- Emergence and spread should be included in Prevent rather than Tackle
- The contribution to the objectives of the EU Action plan against AMR should be better highlighted

Do you consider that the research and innovation objectives, listed under each thematic area, are relevant for the OH AMR Partnership?

36 responders (85,7%), replied Yes to the question whether the research and innovation objectives are relevant for the OH AMR Partnership.

Comments on Research and Innovation Objectives

We would like to emphasise that more details on the Research and Innovation Objectives is found in the long version that can be found here: <u>Research and Innovation</u> <u>Objectives of the SRIA</u> (pdf 2 MB)

The comments below is a non-exclusive list, but all comments received have been considered in the revision of the SRIA.

- Better connection with the GOs, SOs and OOs are needed
- Leave open to other pathogens than bacteria and fungi
- Focus more on societal benefits
- Learn from the Covid-19 pandemic and other sectors
- Therapeutics: Include also vaccines
- Therapeutics: Explore existing and neglected antibiotics and address antibiotic shortages
- Therapeutics: Include also data-mining search in the big data and three-dimensional structural predictions on novel targets
- Diagnostics: there is a requirement to understand the needs of end users, target to specific groups
- Diagnostics, Surveillance and Transmission: Add also detection of AMR in nonpathogenic microorganisms and surveillance of healthy populations. Clarify whether transmission and evolution mechanisms will be studied also in non-pathogenic microorganisms
- Surveillance: Include the healthcare professional perspective
- Surveillance: Highlight the importance of environmental monitoring in water and relate to the revised EU water legalisation
- Surveillance: Ensure that there is no overlap in what for example ECDC, OECD and EDCTP3 are already doing. Focus on prioritised pathogens.
- Surveillance: Facilitate data transfer and harmonisation but note that some reporting protocols already exist
- Surveillance: Integrated surveillance should be further explored
- Surveillance: Clarify whether the focus will be on EU or also globally
- Surveillance: How do you envisage to overcome economic barriers?
- Surveillance and Transmission: Better link between these areas
- Transmission: Include how better understanding of mechanisms will help designing new drugs
- Transmission: Include research on co-selection, how exposure of one antimicrobial class can preserve resistance to another
- Intervention & Prevention: Target R&I to actual needs. Intervention strategies may be totally different depending on context
- Intervention & Prevention: The objectives are too vague and should include new technologies for IPC as well as behavioural research on why guidelines are not adhered to
- Intervention & Prevention: Include also prevention of contamination by biocides and metals
- Intervention & Prevention: Consider also the effect of water recycling in agriculture

Have the cross-cutting issues been well described and integrated in the Research and Innovation objectives?

31 responders (75,6%) replied Yes to the question whether the cross-cutting issues have been well described and integrated in the Research and Innovation objectives.

Comment on the cross-cutting issues

- integrate the cross-cutting better in each thematic area
- open data/open access need to be described in more detail, including barriers
- Social sciences: behavioural and economic aspects are not well addressed and should not only be seen as a complementary element
- International: risks imported by trade and travel (from extra EU) have to be addressed better
- One Health: include the full food supply chain, not only farmers, and also include crops
- One Health: specify the actions on environmental aspects further and emphasise these aspects further
- Innovation: Clarify these aspects further, integrate it more in the research and include also innovative preclinical in vitro models. Not clear how industry will be involved

Foreseen activities and portfolio of instruments

Is the proposed portfolio of funding instruments sufficient for fulfilling the aims and objectives of the partnership?

34 responders (85%) replied Yes to the question whether the proposed portfolio of funding instruments is sufficient for fulfilling the aims and objectives of the partnership.

Comment on funding instruments

- too much focus on networking rather than research
- respect also fundamental research and have a rather broad scope of the calls
- enhance intersectoral collaboration for each of the objectives under each thematic area, including capacity building and communication
- add partnerships to build an enabling environment for generating innovation and its uptake by facilitating partnerships between Europe and non-European OH AMR program managers, funders/donors, researchers, civil society and others
- add financing for infrastructures
- include call exclusively focusing on young researchers
- include modules on environment and animals/agriculture
- if different funding instruments are developed under the same call, please pay attention to make it easy (both for the applicants and funders)
- clarify the definition of early career researchers

Are the proposed transversal activities sufficient for fulfilling the aims and objectives of the partnership?

37 responders (90,2%) replied Yes to whether the proposed transversal activities are sufficient for fulfilling the aims and objectives of the partnership.

Comments on transversal activities

- include interaction with regulators and establish European regulatory networks
- include elements to strengthened cross-sectoral capacity and collaboration across sectors, promote learning and exchange between sectors for the collective generation of knowledge and solutions.
- include harmonization of analytical methods, protocols, assessments and reports; survey of the quantity flows
- communication efforts are very important and could be more elaborated
- emphasise the co-funding by the EC and the measures that will be implemented for widening measures in the Joint Transnational Calls
- important to work closely with and learn from other partnerships and not duplicate transversal activities

Synergies and engagement with other partnerships, initiatives and stakeholders

Are the other European partnerships mentioned relevant for the OH AMR partnership for promoting synergy and engagement?

36 responders (87,8%) replied Yes to whether the partnerships mentioned are relevant for the OH AMR partnership.

Comments on other partnerships, initiatives and stakeholders

- important to do a more thorough analysis and organise dedicated meetings with other initiatives to ensure no overlap, consider reciprocal representation in governing boards or stakeholder boards
- important to understand what for example EU agencies are already doing in terms of surveillance
- suggestions to include the EU AMR One Health Network, the Partnership on Agriculture of Data, EPI-NET, EFPIA, AMR Action Fund, AMR Industry Alliance., BARDA, INCATE, European Health Data Space, Digital Europe
- include also national initiatives and valorisation of national projects
- highlight Personalised medicine and initiatives on water, sanitation and hygiene
- take into account also additional potential future partnerships
- Not clear that the European partnerships mentioned here will be able to sufficiently cover late stage development (phases 2 and 3)
- identify also European Research Infrastructures and their projects
- Biodiversa+ might be less relevant

General comments on the SRIA

- The research agenda is extremely broad and it might be hard to steer/focus the research to particularly important areas
- The One Health approach does not have the expected prominent position in the SRIA
- OK for mentioning One Health, but don't push it too hard. A lot of aspects in addressing AMR remain sectorial: IPC measures, diagnostic tests, novel therapeutic options, etc.
- involve experts working in public health in research projects that include the public health sector or its interface
- we consider this Partnership a unique opportunity to act as a backbone of the multiple initiatives and programs focus on tackling AMR. It could have an important role in building bridges between similar programs and joining forces.
- it would be good to clarify the scale of the different thematic areas relative to each other
- we would welcome more granularity in the description of priorities in term of medical countermeasures (treatment, vaccine, diagnostics) taking into account the current unmet medical needs.

Consultation Workshop on the OH AMR SRIA

As part of the consultation process, a workshop was performed 20 April 2023, 2-4 PM CEST, mainly directed to funding agencies and organisations that have expressed interested in becoming partners of the EUP OH AMR.

The different parts of the SRIA were presented by members of the DESIGN OH AMR consortium:

Overview of the preparation process and the SRIA, Laura Marin, Swedish Research Council (SRC)

Intervention Logic and indicators for monitoring, Patriq Fagerstedt and Shawon Lahiri, SRC

Research and Innovation Objectives, Sophie Gay, French National Research Council (ANR)

Portfolio on Funding Instruments, Živilė Ruželė, Research Council of Lithuania (LMT)

Interactions with other partnerships and initiatives, Susanne Frykman, SRC

Each presentation was followed by a Q&A session and some of the points that were raised were:

- Intervention Logic: clarify how you will achieve increased commitment and investment
- Intervention Logic: quality indicators are needed for the performed research
- R&I objectives: clarify if animal R&I will be included and the link to EUP AH&W
- R&I objectives: important to consider sustainability when developing therapeutics and diagnostics
- R&I objectives: the tools for improved approval processes are already in place, the main problem is the pipeline, important to interact with initiatives such as Carb-X
- Other partnerships and initiatives: Apart from EOSC, consider to also interact with the Joint Action Towards the European Health Data Space (TEHDAS)

Conclusion

We are grateful for all constructive feedback that was achieved from the consultation. Some of the feedback was taken into account when revising the first draft of the EUP OH AMR SRIA before publishing it on 22 May 2023⁶. Other feedback will be very valuable for the development of the Roadmap of Actions, which is expected to be published early 2024 and the second draft of the SRIA, which is expected to be published in the second quarter of 2024.

⁶ <u>First draft of the SRIA of the EUP OH AMR</u> (22 May 2023)