Pre-draft proposal for a European Partnership under Horizon Europe

One Health Antimicrobial Resistance

Version 9 February 2022

About this draft

In the course of 2021 Commission services asked potential partners to further elaborate proposals for the 2023/24 candidate European Partnerships identified during the strategic planning of Horizon Europe. These proposals have been developed by potential partners based on common guidance and template, taking into account the initial concepts developed by the Commission and feedback received from Member States during early consultation¹. The Commission Services have guided revisions during drafting to facilitate alignment with the overall EU political ambition and compliance with the criteria for Partnerships.

This document is a stable draft of the partnership proposal, released for the purpose of ensuring transparency of information on the current status of preparation (including on the process for developing the Strategic Research and Innovation Agenda). As such, it aims to contribute to further collaboration, synergies and alignment between partnership candidates, as well as more broadly with related R&I stakeholders in the EU, and beyond where relevant.

This informal document does not reflect the final views of the Commission, nor pre-empt the formal decision-making (comitology or legislative procedure) on the establishment of European Partnerships.

In the next steps of preparations, the Commission Services will further assess these proposals against the selection criteria for European Partnerships. The final decision on launching a Partnership will depend on progress in their preparation (incl. compliance with selection criteria) and the formal decisions on European Partnerships (linked with the adoption of Strategic Plan, work programmes, and legislative procedures, depending on the form). Key precondition is the existence of an agreed Strategic Research and Innovation Agenda / Roadmap. The launch of a Partnership is also conditional to partners signing up to final, commonly agreed objectives and committing the resources and investments needed from their side to achieve them.

The remaining issues will be addressed in the context of the development of the Strategic Research and Innovation Agendas/ Roadmaps, and as part of the overall policy (notably in the respective legal frameworks). In particular, it is important that all Partnerships further develop their framework of objectives. All Partnerships need to have a well-developed logical framework with concrete objectives and targets and with a set of Key Performance Indicators to monitor achievement of objectives and the resources that are invested.

Aspects related to implementation, programme design, monitoring and evaluation system will be streamlined and harmonised at a later stage across initiatives to ensure compliance with the implementation criteria, comparability across initiatives and to simplify the overall landscape.

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https://www.era-learn.eu/documents/final_report_ms_partnerships.pdf

1. General information

1.1. Draft title of the partnership

One Health Antimicrobial Resistance partnership. Acronym: OH AMR (tbc)

1.2. Lead entity (main contact)

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1.4. Summary (max 500 characters)

The OH AMR Partnership aims to coordinate and align antimicrobial resistance (AMR) research activities and funding in Europe and beyond. It will facilitate transdisciplinary co-operation and national coherence on AMR policy between different sectors (e.g. human health, agriculture, environment, innovation). The main goal is to contribute to achieving the objectives of the European One Health Action Plan against AMR² and the World Health Organization (WHO) Global Action Plan on AMR³, by reducing the threat of AMR and contribute to achieving the objectives of the Health Emergency Preparedness and Response Authority (HERA)⁴.

2. Context, objective, expected impacts

2.1. Context and problem definition

Antimicrobial resistance is the ability of microorganisms to resist antimicrobial treatments, especially antibiotics. Antimicrobials are used to treat infections and improve the health of humans as well as pets, plants and livestock.

AMR has a direct impact on human and animal health and carries a heavy economic burden due to higher costs of treatments and reduced productivity caused by sickness. AMR is responsible for an estimated 33,000 deaths per year in the EU, and costs the EU EUR 1.5 billion per year in healthcare expenditure and productivity losses. The latest report from The Lancet on the "Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis" illustrates how antimicrobial resistance (AMR) is a leading cause of death around the world, with the highest burdens in low-resource settings. Indeed, AMR is recognised as major threat to the health of citizens and societies at the highest political levels undermining the attainment of the Sustainable Development Goals (SDGs). International fora (e.g. WHO, UN Interagency

² https://ec.europa.eu/health/system/files/2020-01/amr 2017 action-plan 0.pdf

³ https://www.who.int/publications/i/item/9789241509763

⁴ https://ec.europa.eu/health/system/files/2021-09/hera_2021_decision_en_0.pdf

⁵ https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02724-0/fulltext

Coordination Group, G7, G20) have stressed and reported that AMR is a global challenge requiring a global and coordinated response. The EU One Health Action Plan against AMR further highlights the need for European and global cooperation. Combatting AMR requires a One Health approach, recognising that human and animal health are interconnected, that diseases affected by AMR are transmitted from animals to humans and vice versa. This approach encompasses the environment as a link between humans and animals and a reservoir of resistant microorganisms. It also takes into account socio-economic drivers that affect the use of antimicrobials in human and animal healthcare to inform best practices for implementing schemes on prudent use.

Unilateral research initiatives can hamper scientific progress since they may lead to a fragmented research landscape and duplications of efforts. Several efforts have been made, particularly within the Joint Programming Initiative on AMR⁶ (JPIAMR) to coordinate research actions addressing gaps and needs identified in a joint Strategic Research and Innovation Agenda (SRIA), but there is room for improvement in strengthening the One Health approach and in broadening the coordination, also in line with the objectives and tools of the European Research Area (ERA).

2.2. Common vision, objectives and expected impacts

The common vision is to improve the EU's response to fight the rise of AMR with a One Health approach by better coordinating funding for research and innovation at EU, national (and regional) level and aligning internationally towards common objectives and an agreed Strategic Research and Innovation Agenda (SRIA) which the future Horizon Europe Coordination and Support Action Design OH AMR, expected to start during the first half of 2022, will be tasked to develop. It is also to contribute directly to EU priorities and the UN Sustainable Development Goals, and to deliver on the targets defined in the European OH Action plan against AMR.

Aligned around a multi-annual SRIA with common objectives for research and innovation on One Health AMR, the prospective partners – in close collaboration with other relevant actors – will define research needs in the medium- to long-term and develop a prioritised joint research programme.

Objectives

- Contribute to achieving the objectives of the European One Health Action Plan against AMR, the WHO Global Action Plan on AMR and the Health Emergency Preparedness and Response Authority (HERA)
- Recognize and strengthen the holistic One Health approach
- Reinforce Europe's leading role in the fight against AMR by adding value to, and leveraging Member State actions.
- Contribute to building a coherent ERA, enabling Member States, Associated Countries and the European Commission to jointly support research and innovation on AMR.
- Identify areas of unmet need and incentivise national/regional funders to commit and invest in transnational AMR research with a comprehensive One Health approach.

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⁶ https://www.jpiamr.eu/

 Decrease fragmentation by boosting alignment of national research, and funding research projects and initiatives and improving EU and global coordination of research activities as well as collaboration between international initiatives.

Expected impacts

- Novel solutions to prevent and treat infectious diseases affected by AMR, improved diagnosis and control of the spread of resistant microorganisms, testing and validation of such solutions and facilitating their uptake or implementation.
- Decreased burden of infectious diseases, notably due antimicrobial resistant pathogens and progress towards Sustainable Development Goal No. 3 'Ensure healthy lives and promote well-being for all at all ages'.
- Closed knowledge gaps on AMR (including those identified in the European One Health
 Action Plan against AMR and the EU Strategic Approach to Pharmaceuticals in the
 Environment), support provided to regulatory science and inform policymaking.

2.3. Necessity for a European Partnership

Research, development and innovation can deliver scientific advice for policymaking, provide novel solutions and tools to prevent and treat infectious diseases affected by AMR, improve diagnosis, and control the spread of resistant microorganisms. Therefore, a comprehensive research approach developed by the MS in agreement and cooperation with the EC in a partnership using a One Health approach will be important to address this problem.

The European One Health Action plan provides the framework within which this partnership can be developed, since its actions focus on areas with the highest added value for Member States including boosting research development and innovation.

A European partnership on One Health AMR would allow coordinating, aligning activities and funding among countries and the EU. It will also facilitate national coherence between different services/ministries with responsibility for the various aspects of AMR and sectors involved (e.g. human health, agriculture, environment, industry).

It will allow leveraging investments, avoiding unnecessary duplication and should thus provide advantages for scaling up research efforts.

The broad scope of One Health AMR research area requires a level of integration and coordination that cannot be achieved without a partnership.

Therefore, the preparation of the future European Partnership for OH AMR should contribute to build a European Research and Innovation Area (ERA) to rapidly and jointly support research and innovation in the fight against AMR.

The Partnership is expected to build on the existing Joint programming initiative on AMR (JPIAMR), the ERA-Net Cofund JPI-EC-AMR⁷ (ended in 2021) and JPIAMR-ACTION⁸, and the One Health European Joint Programme Cofund⁹ (EJP OH), and work in synergy with other

4

⁷ https://cordis.europa.eu/project/id/681055

⁸ https://cordis.europa.eu/project/id/963864

⁹ https://onehealthejp.eu/

related European Partnerships, notably the future Partnership for Animal Health and wellbeing (PAHW)¹⁰.

2.4. Partner composition and target groups

The partnership on OH AMR should involve as many funders from EU Member States as possible to ensure a strong EU-wide geographical coverage, commitment and cooperation on ongoing, emerging or novel opportunities for advancing AMR research and innovation at EU-level. They should have complementary expertise and policy area ranging from Public Health Organisations, Ministries of Science, Research and Innovation, Ministries of Health, to organisations for Environmental, Agriculture and Animal health matters.

The partnership should be open to public funders at both national and regional level in the EU and in countries associated to Horizon Europe, while it could also consider public funders from third countries. Other non-for-profit funders could get involved in topic specific cofunding activities within the joint research programme and in agreement with the MS.

All partners should have a key role in their respective countries in OH AMR activities.

A larger community of stakeholders, EU and International initiatives related to OH AMR might be linked to the initiative.

3. Planned implementation

3.1. Activities

The OH AMR Partnership aims to be a joint funding initiative that pools together public funders and other public authorities of members countries and the EU that jointly identify and implement common research priorities areas in a joint research programme to advance AMR research.

The Horizon Europe DESIGN OH AMR Coordination and Support Action (under Grant preparation in Q1 2022) will provide the platform for the preparatory groundwork for the candidate European partnership on OH AMR.

It will design an AMR One Health Strategic Research and Innovation Agenda (SRIA), and a Roadmap of Joint Actions that will be implemented through joint transnational calls for proposals and additional activities within the Partnership from 2025 and onwards.

The One Health AMR Partnership will support research and innovation for contributing to the prevention and reduction of AMR and the development and safeguarding of effective antimicrobial treatment and interventions for human and animals.

It will build on the existing network of JPIAMR research funders expanding it further to include additional funders, as well as and engage with policy makers, relevant national agencies, European partnerships, such as OH EJP, under Horizon 2020 and Horizon Europe Framework Programmes and other stakeholders.

A work programme for the first two years of the OH AMR partnership will be drafted and developed through the DESIGN OH AMR project, based on the Roadmap of Actions. The

 $^{^{10}\} https://ec.europa.eu/info/research-and-innovation/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/european-partnerships-horizon-europe/candidates-food-security_en$

OH AMR Work Programme for the first two years will include a comprehensive overview of actions that will be implemented within the OH AMR partnership for the first year (2025), including calls, workshops and other activities. Future work programmes in the OH AMR partnership will be drafted during the OH AMR partnership on an annual basis.

The Activities of the Partnership will be divided in 3 main areas:

1. Align Research

The Partnership will mobilise and link key AMR stakeholders, encompassing the human, veterinary, agricultural and environmental disciplines and including a broad spectrum of pathogens, bacteria, fungi, parasites and viruses, through a cross-cutting, interdisciplinary one health approach. It will provide a framework to close the current knowledge gaps and break existing silos in the AMR research landscape, facilitating the integration of national and international scientific and policy communities with industry and the civil society.

Activities

- Joint strategic programming and global coordination of research and innovation through an agreed One Health AMR SRIA (covering the scientific areas Therapeutics, Surveillance, Diagnostics, Transmission, Prevention and Intervention).
- Target research and innovation efforts to actual needs (challenge-driven) of policymakers and stakeholders
- Create a transnational system that supports collaboration between EU, MS and international initiatives

2. Boost Research

The Partnership will strengthen the ERA by funding excellent and innovative research, capacity building, programmes for development of talent and research opportunities everywhere in Europe and beyond and measures to facilitate re-use and sharing of data.

Activities:

- Support excellent global AMR research and development of new prevention methods, interventions, treatments and diagnostics through annual joint transnational research calls and research network calls
- Develop new tools and instruments to support research and innovation
- Support networking, training and mobility of researchers
- Facilitate sharing and use of data and research infrastructure

3. Develop solutions

- Facilitate translation of scientific knowledge into innovations solutions
- Connect, merge and align dissemination of outputs with other initiatives to support evidence-based policy in whole One Health domain
- Societal engagement by bridging science to society creating awareness of AMR challenges, value creation, support the wellbeing of citizens and sustainability of the environment

Interfaces and relationships with other European Partnerships and international initiatives

The Partnership will identify, engage and explore links with other relevant candidate and existing European partnerships, international AMR initiatives and other stakeholders in order to seek synergies,

develop strategies, and to plan joint actions and collaborative activities essential for the successful implementation of the OH AMR partnership.

It will identify multiple interconnections and potential joint actions between the candidate and existing European Partnerships, both within and between the clusters of the Horizon Europe Framework Programme, as well as with other existing European research and innovation programmes and initiatives. These actions intend to:

- Strengthen the ongoing collaboration with key initiatives in the human therapeutics area regarding the funding landscape for the antibiotic pipeline.
- Seek cooperation with new actors / partnerships in the human therapeutics field through building interactions with the candidate European partnership on Pandemic Preparedness(potentially through a joint working group (WG) that is currently under discussion) and the candidate European partnership on Personalised Medicine ¹¹, the Innovative Health Initiative ¹² (exchanges on the development of the OH AMR SRIA are ongoing), the Global Health EDCTP3 Joint Undertaking ¹³; Health Emergency Preparedness and Response Authority (HERA).
- Expand collaborations to key players in the animal health, agriculture and environment fields including the candidate European partnerships "Animal, Health and Welfare" (PAHW) (a joint WG with OHEJP has been developed to align both partnership SRIAs), "Rescuing biodiversity to safeguard life on Earth", "Safe and Sustainable Food Systems", "Water Security for the Planet" (Water4All)¹⁴, and the candidate European partnership on "Agroecology living labs and research infrastructure"¹⁵.
- Strengthen exchange of information with the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) and expand discussions to include other agencies.
- Identify a One Health collaboration with key international organisations including the WHO-FAO-OIE Tripartite.
- Build further on the monthly exchange meetings with WHO and develop existing
 collaborations (e.g. the Strategic and Technical Advisory Group for Antimicrobial resistance
 (STAG-AMR), Antifungal Expert Group, Global OH AMR agenda) and extend engagement with
 Food and Agriculture Organisation of the United Nations (FAO) and the World Organisation for
 Animal Health (OIE).
- Engage with the Tripartite "AMR Multi-stakeholder Partnership Platform".

Framework for monitoring and evaluation of the OH AMR partnership

Different activities and actions on AMR have been planned with key stakeholders, organisations and initiatives to generate concrete outcomes in preparation for the OH AMR partnership. The European partnerships will be guided by a coherent set of criteria across their lifecycle, including guidance

¹¹ https://ec.europa.eu/info/research-and-innovation/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/european-partnerships-horizon-europe/candidates-european-partnerships-health_en

¹² https://www.imi.europa.eu/about-imi/innovative-health-initiative

¹³ https://www.edctp.org/news/legal-basis-for-global-health-edctp3-joint-undertaking-adopted/#

¹⁴ https://ec.europa.eu/info/research-and-innovation/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/european-partnerships-horizon-europe/candidates-food-security en

¹⁵ https://ec.europa.eu/info/research-and-innovation/research-area/agriculture-forestry-and-rural-areas/partnership-agroecology_en

regarding implementation and expected impact. A recalibration of the existing "Monitoring and Evaluation framework of JPIAMR" is needed to meet the monitoring and evaluation criteria to be outlined by the EC to monitor the progress of the future European partnerships as a policy approach.

Activities:

- Set up transparent and inclusive processes in close cooperation with the future members of the partnership for establishment and/or revision of the monitoring framework.
- Identify and include relevant stakeholders in the process to discuss and validate the indicators and proposed measurement methods for monitoring and evaluation.
- Set up the common principles and criteria for a monitoring and evaluation framework covering the lifecycle of the OH AMR partnership

3.2. Resources

To be developed

3.3. Governance

To be developed

3.4. Openness and transparency

The Partnership will maximise its impacts by involving all relevant partners and stakeholders and by remaining open during its lifetime. In this view, establishing a dialogue and promoting networking and synergies with all relevant actors in the area of OH AMR will be crucial to foster transparent communication, increase mutual awareness and trust for the benefit of the EU Partnership on OH AMR. The identification, contact and dialogue with potential national and funding organisations will be explored, firstly from countries already involved in the preparatory CSA and the JPI AMR. The CSA will target its attention to organisations within the EU, as well as in other parts of the world. Collaboration with the latter will be pursued, not only because they may face similar challenges, but most importantly because they may have developed solutions of potential value to Europe, and vice versa.

Targeted stakeholders will be involved by inviting selected experts in the area of pandemic preparedness to attend key meetings concerning the CSA activities, via face-to-face meetings or predominantly by electronic/technological means. In addition, at wider scale, information about the initiative and provision of relevant updates will be done making use of the Project newsletters and other materials /information in order to reach other potential prospective partners.