



European initiatives on One Health AMR research and innovation

AMR One Health Network (OHN)

25 & 26 JANUARY 2022

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MAKING THE EU A BEST PRACTICE REGION ON AMR

- Better evidence and awareness
- Better coordination and implementation of EU rules
- Better prevention and control
- Better addressing the role of the environment
- A stronger partnership against AMR and better availability of antimicrobials



BOOSTING RESEARCH, DEVELOPMENT AND INNOVATION ON AMR

- **New economic models & incentives**
- Better detection and control measures
- **New antimicrobials, rapid diagnostic tests, vaccines & alternative therapies**
- AMR in the environment



SHAPING THE GLOBAL AGENDA ON AMR

- Stronger EU global presence, partnering
- Stronger bilateral partnership for stronger cooperation
- Cooperating with developing countries
- Developing a global research agenda

Horizon Europe

The ambitious EU research and innovation framework programme (2021-2027)



fuel EU's **scientific and technological excellence** and the strengthen the European Research Area (ERA)

**Science
& technology**



tackle policy priorities, including **green and digital transitions** and Sustainable Development Goals

Society



boost Europe's **innovation uptake, competitiveness** and **jobs**

Economy

HORIZON EUROPE

EURATOM

SPECIFIC PROGRAMME: EUROPEAN DEFENCE FUND

Exclusive focus on defence research & development

Research actions

Development actions

SPECIFIC PROGRAMME IMPLEMENTING HORIZON EUROPE & EIT*

Exclusive focus on civil applications



Pillar I EXCELLENT SCIENCE

European Research Council

Marie Skłodowska-Curie

Research Infrastructures



Pillar II - €58.9 billion GLOBAL CHALLENGES & EUROPEAN INDUSTRIAL COMPETITIVENESS

Clusters

- **Health – €8.25 billion**
- Culture, Creativity & Inclusive Society
- Civil Security for Society
- Digital, Industry & Space
- Climate, Energy & Mobility
- Food, Bioeconomy, Natural Resources, Agriculture & Environment

Joint Research Centre



Pillar III INNOVATIVE EUROPE

European Innovation Council

European Innovation Ecosystems

European Institute of Innovation & Technology*

WIDENING PARTICIPATION AND STRENGTHENING THE EUROPEAN RESEARCH AREA

Widening participation & spreading excellence

Reforming & Enhancing the European R&I system

Fusion

Fission

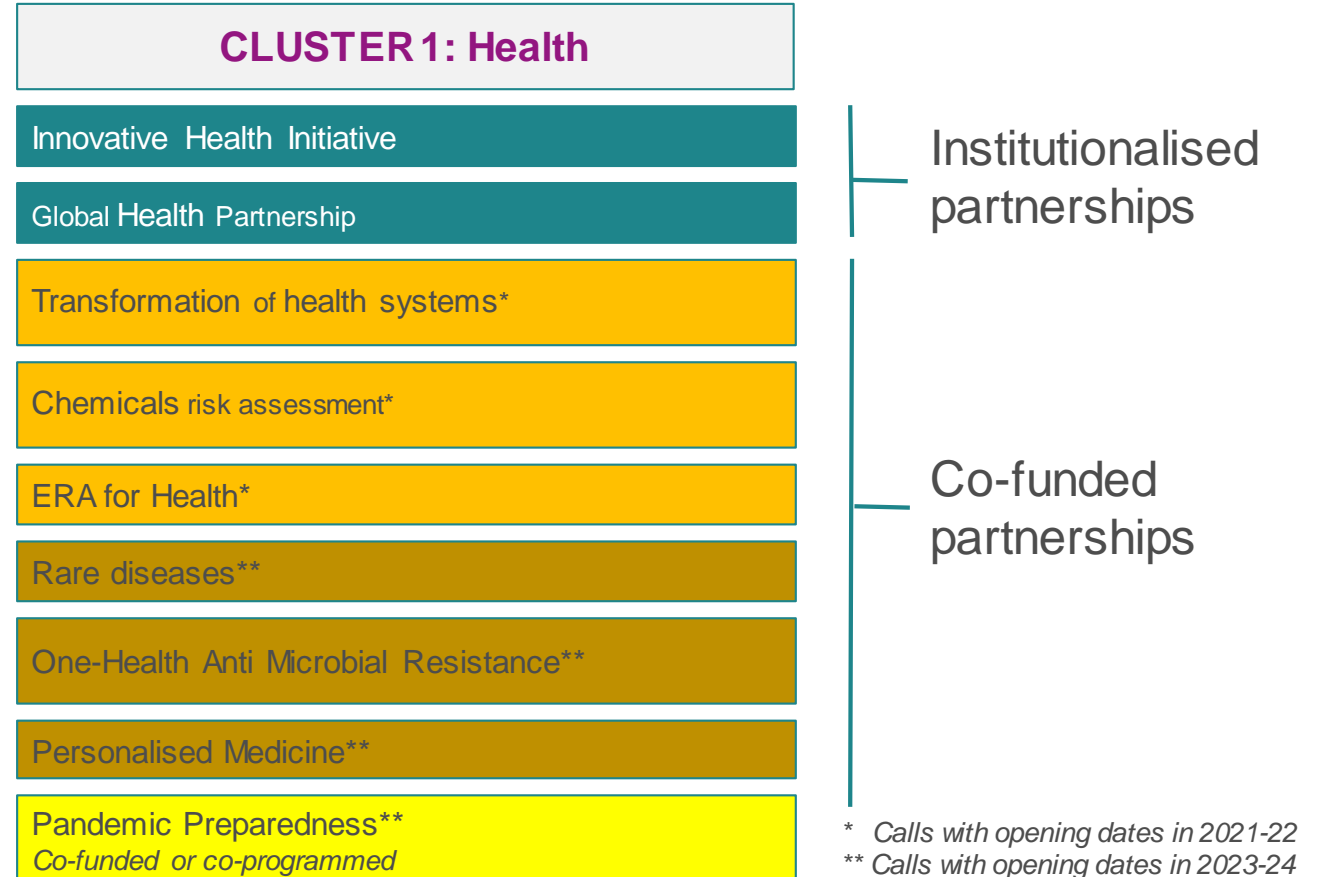
Joint Research Center (JRC)

* The European Institute of Innovation & Technology (EIT) is not part of the Specific Programme

Horizon Europe – 49 European Partnerships

Partnerships

- Strategic Plan identifies 49 co-programmed and co-funded partnerships:
 - public-public;
 - public-private;
 - global initiatives.
- EC proposals for 10 institutionalised partnerships based on Art 185/187



HE Cluster 6 (Food, bio economy, agriculture...)

Planned Co-Funded Partnership Animal Health and Welfare (PAHW)

Addressing the global problem of AMR

THE LANCET

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ARTICLES | ONLINE FIRST

Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis

Antimicrobial Resistance Collaborators[†] • Show footnotes

Open Access • Published: January 19, 2022 • DOI: [https://doi.org/10.1016/S0140-6736\(21\)02724-0](https://doi.org/10.1016/S0140-6736(21)02724-0)

Check for updates

PDF [3 MB] Fig

Summary

Introduction

Methods

Results

Background

Antimicrobial resistance (AMR) poses a major threat to human health around the world. Previous publications have estimated the effect of AMR on incidence, deaths, hospital length of stay, and health-care costs for specific pathogen–drug combinations in select locations. To our knowledge, this study presents the most comprehensive estimates of AMR burden to date.

Findings

On the basis of our predictive statistical models, there were an estimated 4.95 million deaths associated with bacterial AMR in 2019, including 1.27 million deaths attributable to bacterial AMR. At the regional level, we estimated the all-age death rate attributable to resistance to be highest in western sub-Saharan Africa, at 27.3 deaths per 100 000

The European and Developing Countries Clinical Trials Partnership (EDCTP3)

AMR falls
within the
scope of
EDCTP3

Objectives

To advance the development and use of health technologies, to strengthen health research and innovation capacity in sub-Saharan Africa, to reinforce alignment of national funding in sub-Saharan Africa and to strengthen epidemic preparedness in sub-Saharan Africa and globally.

Partnership between the EU and EDCTP the Association (representing European and sub-Saharan countries)

EDCTP participates actively in the strategic efforts to accelerate the **regulation of safe, quality and affordable medical interventions in Africa:**

- Supports strengthening the ethics and regulatory capacity in 27 sub-Saharan Africa countries
- Is a member of the African Medicines Regulatory Harmonisation Partnership Platform
- Has a long-term working relationship with WHO-AFRO and its African Vaccine Regulatory Forum, most members of AVAREF Technical Advisory Committee have been trained through the EDCTP fellowship scheme
- Is member of the African Medicines Quality Forum

A roadmap towards the creation of the European partnership on One Health antimicrobial resistance

HORIZON-HLTH-2021-DISEASE-04-05

Evaluation on-going, expected results: End of January 2022

Expected outcome

- **Research funders, policy makers, relevant agencies and authorities, and the research community** have a **Strategic Research and Innovation Agenda (SRIA)** to be implemented by the expected future European partnership on One Health antimicrobial resistance (OH AMR).
- **Research funders, policy makers, relevant agencies and authorities, and the research community** profit from a **strengthened coordination and collaboration among different fields of research and innovation with relevance to antimicrobial resistance (AMR)** maintaining Europe's leading role in combating AMR.
- **Academics, innovators, end-users, researchers, public health authorities and citizens** form a **strong ecosystem that improves the implementation of the European One Health AMR strategy** and its contribution to the Sustainable Development Goals.
- **Research funders, policy makers, relevant agencies and authorities, and the research community** are in a position to **close the current gaps and break existing silos on AMR in accordance with the European One Health Action Plan against AMR**

A roadmap towards the creation of the European partnership on One Health antimicrobial resistance

Scope 1/2

Proposals **should cover all of the following activities:**

- ✓ Develop a **Strategic Research and Innovation Agenda (SRIA)** for a comprehensive approach to **inform the expected future European partnership on One Health antimicrobial resistance (OH AMR).**
- ✓ **Integrate key actors for AMR encompassing the field of human, veterinary and environmental disciplines and the broad spectrum of pathogens**, including fungi and viruses.
- ✓ Establish **robust communication and effective information exchange between diverse scientific disciplines and among multiple sectors of the society** (as patients, clinicians, veterinarians, pharmacists, food producers, pharmaceutical industry, policy makers and researchers (including those working in the social sciences and humanities))

A roadmap towards the creation of the European partnership on One Health antimicrobial resistance

Scope 2/2

- ✓ **International cooperation** encouraged, including with low- and middle-income countries where AMR is highly prevalent and prone to spread to Europe.
- ✓ Proposals should **build on, be complementary to and go beyond existing initiatives** such as the JPIAMR, the One Health EJP and ICARS.
- ✓ **Implement collaborative activities with International organisations** such as the World Health Organization, the World Animal Health Organisation (OIE), the Food and Agriculture Organization (FAO), and the G7 and G20 fora, with the aim to avoid duplication of efforts.

The **proposal** should be **ambitious in its inclusiveness**, encompassing the broad spectrum of pathogens, and **mobilise experts from diverse disciplines** to address: understanding, prevention, monitoring, epidemiology, treatment and detection of AMR.

The **consortium** should be **pan-European** with a **large geographical coverage of European countries**

AMR in the Pharmaceutical Strategy for Europe



Flagship initiatives related to antimicrobial resistance

- ▶ Pilot innovative approaches to EU R&D and public procurement for antimicrobials and their alternatives aiming to provide pull incentives for novel antimicrobials – target date 2021.
- ▶ Promote investment and coordinate research, development, manufacturing, deployment and use for novel antibiotics as part of the new EU Health Emergency Response Authority, prior to the start of the authority's operations preparatory action on AMR – 2021.

Innovation partnership

In the past, a contracting authority wishing to run a procurement procedure that combines both development and purchase elements encountered a myriad of difficulties in structuring a competition that did not infringe upon the principles of equal treatment and transparency.

The new **innovation partnership** allows for the **combination of development and purchase elements tailored to public requirements**, with specific rules in place to ensure equal treatment and transparency.



Development, procurement and responsible management of new antimicrobials

HORIZON-HLTH-2021-IND-07-02

Scope: ..prepare for the **establishment of a pull incentive** for new antimicrobials where there is an unmet public health need and a market failure. In line with the **Pharmaceutical Strategy for Europe** innovative approaches at EU level should be developed for **supporting research, development and public procurement of antimicrobials** ...potential procurers of new antimicrobials in the Member States have to set out the requirements and conditions for the final product(s) to be developed and purchased...

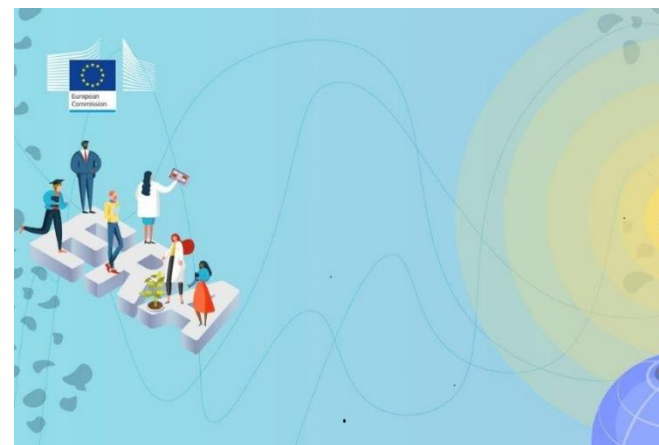
Pandemic preparedness partnership objectives



Improve EU's preparedness to prevent, predict and respond to epidemics / pandemics



Develop Strategic Research and Innovation Agenda (SRIA) on preparedness



Build a European Research Area (ERA) in pandemic preparedness

Pandemic preparedness partnership

areas of activities

New scientific knowledge	Design and develop countermeasures	New strategies for public health response	EU-wide infrastructures	Synergy with HERA and sustainability
<ul style="list-style-type: none"> ➤ Biology of the pathogens, its characteristics and transmission ➤ Better application of enabling technologies ➤ Interaction with host ➤ Role of environment ➤ One health approach 	<ul style="list-style-type: none"> ➤ Preventive measures ➤ Vaccines, diagnostics, therapeutics, PPE ➤ Monitoring tools at population level ➤ Digital solutions ➤ Solutions to increase Europe's strategic autonomy 	<ul style="list-style-type: none"> ➤ Modelling of measures and their impact on societal resilience ➤ More agile public health response ➤ Tackle misinformation ➤ Data analytics, AI and robotics for pandemic management 	<ul style="list-style-type: none"> ➤ EU wide vaccine trials, pan European cohorts and data portals ➤ Improved data collection methodology and tools, data sharing and harmonisation accross sectors 	<ul style="list-style-type: none"> ➤ Scoping and synergy with HERA ➤ Synergies with other partnerships (OH AMR, ...) ➤ International collaboration ➤ Sustainability



Vaccines 2.0-developing the next generation of vaccines

HORIZON-HLTH-2022-DISEASE-06-03

Expected outcomes

- **The scientific and clinical communities** use the increased **knowledge on pathogens** and better **understanding of the immune system's role in infectious diseases** to develop vaccines with improved efficacy.
- **Vaccine manufacturers** use **more innovative and sustainable manufacturing technologies** and **improved GMP manufacturing know-how** for producing the next generation of vaccines.
- **A diversified portfolio of vaccine candidates ready for testing in clinical trials** help **policy makers and funders** to make informed decisions about support to vaccine development.
- **New innovative and improved design of preclinical/clinical studies** that match the features of the next generation of vaccines is available for **clinical community and regulators**, and will shorten vaccine development time.



Vaccines 2.0-developing the next generation of vaccines

Scope

- Proposals should aim to **diversify and accelerate the global vaccine research and development pipeline**, and to **strengthen the current leading role of the EU in vaccine research and development**.
- ... **pathogens, which still lack vaccines of sufficient efficacy**, but where earlier efforts have already produced promising vaccine candidates.
- Innovation and integration of expertise and capabilities, including **alignment of preclinical and clinical models, biomarker studies and new vaccine approaches** from discovery to late stage development, from bench-based research to clinical development of promising preventive candidates.
- Application of iterative processes ... to allow **exploitation and integration of novel findings between clinical, preclinical and discovery research and development**.
- Deciphering **mechanisms of protection of candidates**, new **approaches to antigen discovery and immunogen engineering, reverse vaccinology, evaluation of vaccines** in novel platforms and technologies, **novel adjuvants, innovative vaccine manufacturing approaches, relevant animal models**, evaluation of **alternative vaccine delivery routes**.
- **Effective, evidence-based decision-making for progression of vaccine candidates** in the pipeline based on transparent and objective portfolio management.

In addition

- Regulatory requirements need to be considered.
- Sex, gender, age and socio-economic factors should be taken into account.

Thank you

More info: https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/coronavirus-research-and-innovation/treatments_en



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