

JOINT PROGRAMMING INITIATIVE ON ANTIMICROBIAL RESISTANCE

JPI AMR Future Strategy 2020 - 2025 Vision, Achievements and Future

Argentina, Canada, Belgium, Czech Republic, Denmark,

Estonia, Finland, France, Germany, Greece, Ireland, Israel,

Italy, Japan, The Netherlands, Norway, Poland, Romania,

Spain, South Africa, Sweden, Switzerland, Turkey,

The United Kingdom.

May 19, 2017

Executive Summary

The Challenge - Lives Are at Stake

Antibiotics have saved millions of lives throughout the many decades it has been in use as a common drug. However, **antibiotic resistance** is *now* a global health security challenge. When bacteria become resistant to commonly used drugs, society needs to respond with concerted actions. Only together can we divert from a trajectory leading to up to **10 million** human lives being extinguished yearly because of antibiotic resistant bacteria, this by **2050** if projections becomes reality. **Collaboration** is the cornerstone of **JPIAMR** and collaboration is key - resistant bacteria knows of *no* nations boarders. Currently, there are **few new antibiotics in development**.

The JPIAMR - The key to turn the tide of AMR

The Joint Programming Initiative on Antimicrobial Resistance, JPIAMR, is a unique international collaborative platform that coordinates national funding and supports collaborative action for filling knowledge gaps on antimicrobial resistance with a One Health perspective. By mobilising existing and new resources, the JPIAMR creates a greater critical mass and attracts new researchers into the AMR field. Our shared Strategic Research Agenda, outlines the key areas to address and provides guidance for countries to align their AMR research agendas nationally and internationally. This to meet major challenges that *no* individual country is capable to handle on its own. Today 24 countries have joined JPIAMR as members. The collaborative platform is now internationally recognized.

JPIAMR interacts with stakeholders such as WHO, ASEAN, G7 and the USA. G20 and G7 now include activities by JPIAMR in declarations and resolutions. JPIAMR coordinates research priorities and calls with the EC, IMI and pharma industry together with close cooperation with EC DG Research, DG Santé and many efforts aligning with European health authorities. The current platform extends well beyond Europe including members such as Japan, Argentina, South-Africa and other nations. New members are added continuously to this global and unique platform.

The Future – Global Collaboration Creates Transformative Changes

The mission for JPIAMR for the years 2020-2025 is stated as: "To join forces across nations by leading the alignment, coordination, and support to Antimicrobial Resistance One Health collaborative research and global policy activities".

The overarching major goals are:

- To align national and international research programmes.
- To support and coordinate transformative research.
- To support and coordinate the JPIAMR Virtual Research Institute.
- To promote innovation and translation of research results.
- To bridge the gap between research and policy.

JPIAMR **support new evidence and innovations** that reduce the burden of antimicrobial resistance through coordinated global collaborative research in Europe and around the world. Also aiming to undertake further research to better understand how resistance develops and spreads in the environment. And to develop diagnostic tools and better surveillance methods as well as validating smarter strategies for using antibiotics in healthcare and agriculture.

JPIAMR will contribute to *faster global progress* of research and innovation on antimicrobial resistance. To ultimately find new cures and methods to harness drug resistant bacteria. The **Virtual Research Institute** is a dynamic network of research facilities, changing the way resources are shared and used.

The scientific and societal challenge of AMR is likely to be greater in the next 10 years.

JPIAMR is the key to turn the tide of AMR in Europe and beyond.

1. Evolution of the JPI AMR

1.1. General information

Name of the initiative	Joint Programming Initiative on Antimicrobial Resistance
Acronym of the initiative	JPIAMR
Weblink	www.jpiamr.eu ; twitter.com/JPIonAMR
Launch of the initiative	December 2011
Chairperson	Carlos Segovia, Instituto Carlos III, Spain
Chair SAB	Laura Piddock, Birmingham University, UK
Head Secretariat	Laura Marin, Swedish Research Council, Sweden laura.marin@vr.se
Strategic research agenda	V1. December 2013 http://www.jpiamr.eu/document-library/strategicresearchagenda/
Current implementation plan	V2. December 2015: Plan 2014-2018 V3. November2016: Strategic Plan 2018-2020 http://www.jpiamr.eu/document-library/implementation-plan/
Funded projects	http://www.jpiamr.eu/supportedprojects/

1.2. State of play - main milestones

WHY A JPIAMR: The Societal Challenge:

Antibiotics have saved millions of lives. However, antimicrobial resistance (AMR) continues to spread, as overuse and misuse is rendering many antibiotics ineffective. Awareness of the threat of antimicrobial resistance has increased at all levels of society since the formal inception of the Joint Programming Initiative on Antimicrobial Resistance (JPIAMR) in 2011. Antibiotic drug resistance has recently been recognised as a global health security challenge of the 21st century by the G8 science ministers¹ and main international agencies (World Health Organization (WHO), World Organisation for Animal Health (OIE), US and European Centres for Diseases Control and Prevention (CDC & ECDC)², and the International Monetary Fund (IMF)³. Measures to control the problem on a global scale are gathered under the One Health perspective, but all of them, including those highlighted as "urgently needed", demand the "… support of theoretical and applied research to better understand the origin, spread, evolution and development of resistance in microorganisms".

The One Health concept⁴ recognises that the health of people is connected to the health of animals and the environment. A One Health approach is important, because six out of every ten infectious

¹ G8 Science Ministers Statement https://www.gov.uk/government/news/g8-science-ministers-statement

 $^{^2\ \}underline{\text{http://www.cdc.gov/drugresistance/threat-report-2013/}}; \underline{\text{http://ec.europa.eu/dgs/health_food-safety/amr/index_en.htm}}$

³ http://www.imf.org/external/pubs/ft/fandd/2014/12/jonas.htm

⁴ Wallace, R. G., Bergmann, L., Kock, R., Gilbert, M., Hogerwerf, L., Wallace, R., & Holmberg, M. (2015). The dawn of Structural One Health: A new science tracking disease emergence along circuits of capital. Social science & medicine, 129, 68-77; Rüegg, S. R., McMahon, B. J., Häsler, B., Esposito, R., Nielsen, L. R., Speranza, C. I., ... & Davies, P. (2017). A blueprint to evaluate One Health. Frontiers in Public Health, 5.

diseases in humans are spread from animals. It is also important because the problem of AMR is disseminated through humans, animals and the environment.

The rationale for forming the Joint Programming Initiative on Antimicrobial Resistance (JPIAMR) was the recognition of the lack of a joint comprehensive integrated One Health approach to coordinate AMR research in both the development of new therapies and diagnostics, as well as prevention of emergence and transmission of antimicrobial drug resistance. As resistant bacteria know no national borders, JPIAMR is now a global initiative. By engaging nations beyond Europe as members, JPIAMR enables and supports collaborative research and capacity-building actions on an international scale.

WHAT IS JPIAMR: "One Health collaborative platform mitigating AMR"

JPIAMR is an international collaborative platform for nations all over the world, which coordinates national funding and supports collaborative action for filling knowledge gaps on AMR with a One Health perspective. Our Strategic Research Agenda outlines the key areas to address and provides guidance documents for countries to align their AMR research agendas nationally and internationally.

HOW: JPIAMR achieves this by:

- Identifying key knowledge gaps in antimicrobials drug discovery, prevention from infection, and conservation strategies for existing drugs, and the prioritisation of critical research questions to address them.
- Widening European and international participation in JPIAMR and supporting alignment of national and international AMR strategies and research plans.
- Mobilising existing and new resources, creating a critical mass of expertise, supporting capacity-building in less research-intensive countries, and attracting new researchers into the AMR field.
- Coordinating national and transnational AMR funds and creating leverage for increased national funding in joint calls.
- Joint funding decisions to support strategic AMR research projects with a One Health perspective and the dissemination of results to support translation and innovation, and uptake by industry.
- Bridging the science policy gap by facilitating knowledge exchange across sectors to support the translation of research findings into evidence-based measures for societal impact.

JPIAMR current Implementation plan runs until 2018. Based on the strategy 2018-2020 and work plans developed by the JPIAMR Management Board working groups, JPIAMR is redefining its implementation plan until 2020 through a series of exploratory workshops, surveys and policy meetings.

JPIAMR implementation plan 2017-2020 includes:

- Development of a long-term strategic plan, including a sustainable and broadened governance structure that includes veterinary and environmental perspectives and a business plan for JPIAMR activities.
- Widening of the participation of European and non-European countries in JPIAMR activities and expanding the membership globally. Adapting governance structure and membership policies.
- Enhancing the existing relations with national research and health policymakers (research plans/national AMR policies), supranational AMR initiatives at global level (alignment of UN,

WHO, TATFAR and G7/G20 declarations on aspects of research), and **industry** (bridging the gap between pre-clinical and clinical) in order to align objectives, assess needs and identify areas for increased research funding.

- Updating the **Strategic Research Agenda** (SRA) and extending it to include innovation and translational priorities for the exploitation of AMR science.
- Supporting the AMR research community by setting up a global **AMR Virtual Research Institute** consisting of research-performing organisations, providing information on research input and research output, and facilitating the use of infrastructure, by developing an entry-point database.
- Collaborating with national funding agencies and research-performing institutions to support alignment of their activities with the SRA.
- Increasing the visibility and knowledge of the JPIAMR initiative and its funded projects.

JPIAMR Main milestones

2011: JPIAMR launched by **17 countries**. Vision document and terms of reference adopted. Governance structure, central secretariat and scientific advisory board created.

2012: Stakeholder advisory board created. Coordination and support action by EC started. **Israel ioining.**

2013: Strategic research agenda and implementation plan 2014-18 developed. Canada joining.

2014: First joint transnational call launched. Foresight guidelines developed. Evaluation and monitoring framework adopted. **Estonia joining.**

2015: Second joint transnational call launched. AMR research funding mapping published. AMR projects database set. Membership policy adopted. Self-evaluation undertaken. Alignment plan and communication strategy developed. Intergovernmental AMR policy workshop. ERA-Net cofund on transmission launched. Communications strategy developed. **Argentina and Japan joining.**

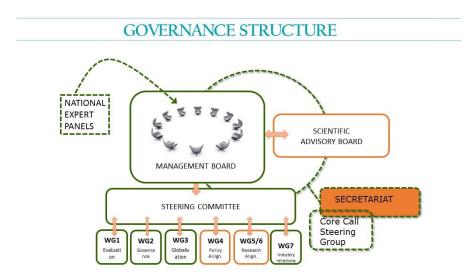
2016: Third and fourth joint transnational call launched. IPR and open access policy. Second coordination and support action started. Joint conference EU-US bringing together big pharma and regulators. JPIAMR membership of IMI strategic group.

2017: Fifth and sixth joint transnational call launched. Peer reviewers database developed. Strategy 2018-2020 developed, roadmap workshops. International strategy developed. **Ireland, South Africa, India joining.**

2018: Expected developments - seventh and eighth joint transnational call. Fellowship programme. Strategic research and innovation agenda updated. New governance models explored. JPIAMR Virtual Research Institute initiated.

1.3. JPI governance

At the moment (May 2017), **JPIAMR has 23 member countries** comprising EU member states, Norway, Switzerland, Canada, Israel, Turkey, Japan, Argentina and South Africa and others joining in 2017, thus becoming a global organisation.



The Management Board (MB) is the main decision-making body and meets two to three times per year. Each member country is represented by two delegates. Implementation of specific areas are handled by strategic "Working Groups". A "Core Call Steering Group" supervises and provides guidance to the Joint Call Steering Groups. Chair: Carlos Segovia (ES), Vice-Chair: Jan-Ingvar Jönsson (SE).

The Steering Committee (SC) provides steering direction and strategic input to JPIAMR. It consists of: Chair: Carlos Segovia (ES), Vice-Chair: Jan-Ingvar Jönsson (SE), and SC Members: Marc Ouellette (CA), Antoine Andremont (FR), Ghada Zoubiane, (UK) and Andreas Aeschlimann (CH).

The Scientific Advisory Board (SAB) advises the MB and JPIAMR on scientific matters, including updating and implementing the Strategic Research Agenda. The SAB is chaired by Professor Laura Piddock, University of Birmingham, UK, and meets twice a year.

The JPIAMR Secretariat of 5FTE is hosted by the Swedish Research Council. It manages JPIAMR' day-to-day activities and the tasks assigned to it by the MB and the SC. It is headed by Laura Marin, Sweden.

1.4. Strategic Research and Innovation Agenda (SRA)

The JPIAMR Strategic Research Agenda (SRA) was developed in 2013, and outlines key neglected areas to tackle, guides JPIAMR strategic actions and priorities, and focuses research actions. The SRA also serves as a guidance document for nations to align their AMR research agenda. It is a major achievement of JPIAMR to create an SRA which has been accepted as a blueprint for many national AMR strategies and action plans, as well as a basis for the development of the WHO Global AMR Research Agenda.

The JPIAMR SRA lists challenges and opportunities within six priority topics that will be translated into new prevention and intervention strategies to improve public health and deliver economic and societal benefits throughout Europe and beyond. The SRA has truly adopted a 'One Health' approach, including animals and the environment in its AMR approach. Acknowledging the role that innovation plays in AMR, the SRA is currently being updated to include different aspects of innovations and to prioritise areas where JPIAMR can add value. The Strategic Research and Innovation Agenda will be updated by 2019.

THE STRATEGIC RESEARCH AGENDA



- 1. **Development** of novel antibiotics and alternatives for antibiotics from basic research to the market.
- 2. Design strategies to improve treatment and prevention of infections by developing new **diagnostics**.
- 3. Standardisation and extension of **surveillance** systems to establish a global surveillance program on antibiotic resistance and antibiotic use.
- 4. To understand the **Transmission** dynamics and to develop evidence-based strategies to minimise the spread of resistance
- 5. The role of the **environment** as a source for the selection and spread.
- 6. Designing and testing **interventions** to prevent acquisition, transmission and infection caused by AMR.

1.5. Joint transnational activities and achievements

KEY ACHIEVEMENTS until 2016: Aligning resources by developing a collaborative platform and maximising existing and future efforts to combat AMR.

- JPIAMR has become a One Health One World collaborative platform, extending its membership beyond Europe, but still with a strong emphasis on widening its base and including European non-members in JPIAMR activities (Latvia and Portugal take part in joint calls). It is engaging with international stakeholders including WHO, the US National Institute of Health (NIH) and Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) organisations, the Association of Southeast Asian Nations (ASEAN) and the G7. JPIAMR activities are included in the G7 and G20 AMR declarations, in the WHO AMR Global Action Plan and in the latest UN AMR resolution.
- Adopting a 'One Health' approach with a Strategic Research Agenda and an Implementation Plan. This approach is also the basis for development of the WHO Global AMR Research Agenda. It is a globally well-accepted framework that encompasses all the areas that need to be covered, as well as their interlinking elements, to fight AMR in a research roadmap.
- The mapping of AMR research and associated investment in member countries published as an article in 'The Lancet' had a strong structural effect, giving an overview of national AMR research capacity and also identifying gaps in funding and the key areas for international collaboration. The results are available online in an AMR projects database and have been instrumental in exploring opportunities for both joint transnational and national calls. It helps to identify the complementarities and capacities across Europe.
- Alignment of resources and national programming by creating a collaborative platform, maximising existing and future efforts to combat AMR by organising 13 international strategic scoping workshops and supporting the development of national expert panels and national policy level inter-sectoral groups. 22 countries today have national AMR plans and strategies aligned to the JPIAMR SRA.
- Coordinating international research and innovation initiatives by linking with the European Commission (DG Research and DG Santè), in the US with NIH, BARDA, and CARBX, and through the high-level group TATFAR, as well as with the pharmaceutical industry (IMI, EFPIA, BEAM), through a dedicated working group, regular meetings and joint workshops with starting conversations to develop a global AMR clinical trial network (Stockholm 2016, Paris 2017).

AN	TIBIOTIC DRUG DEVELOPMENT	TAND INTERNATIONA	L FUNDING INITIA	TIVES
Basic Science	Pre-clinical	Phase I	Phase II	Phase Market
JPIAMR				
National Sc	ience Research Agencies			
EC FP / ERC				
	IMI / ND4BB			
			BARDA	
NIH / NIAI	D			
Wellcome	Trust			
	CARB-X			
(GARDR-P			
			EIB's InnovFin	
UK / China	a Global Innovation Fund			
	Existed Prior 2016	Recenly Launched		

• Funding research that both makes an impact and adds value. Five joint research calls have been launched since 2014, with commitment of up to 55 million EUR of funding secured. Projects funded will hopefully lead to the discovery of new targets and drug candidates, new options for treatment using combinations of neglected antibiotics, and new knowledge on transmission of resistant bacteria and resistance genes between human, animals, and the environment.

JOINT CALLS FOR RESEARCH PROPOSALS

Year	Participatin g countries	Funded MS (M€)	Funded EU (M€)	Research topic	No. of Projects funded
2014	12	8.1	0	InnovaResistance	7 projects/41 partners
2015	9	4.5	0	Repurposing Neglected Antibiotics	3 projects/17 partners
2016	19	21.84	6.30	Transmission and Selection of Resistance in Humans, Animals, and the Environment (ERAnet Cofund)	19 projects/96 partners
2016	10	0.65	0	Transnational Working Groups Call	13 networks/160 partners
2017	15	13,0 (budget)	0	Comparison of prevention, control, and intervention strategies for AMR infections through multidisciplinary studies including One Health approaches.	Under review
2017	tbd	tbd	0	Fellowship Program	under development
2018	>16	>20	0	Therapeutics Surveillance Network Call	under development
Total		47.59	6.30		42 projects/networks 314 partners

- A very cost-effective JPIAMR working group call engaged 160 research groups through 13
 networks to focus areas related to antibiotic stewardship, standards for veterinary
 antimicrobial susceptibility testing, rapid diagnostic testing and alternatives to antibiotics.
- JPIAMR is attracting more researchers into the field, increasing critical mass and international scientific cooperation. It also has promoted the launch of new national AMR research programmes in several countries, created new networks and delivered policy papers addressing knowledge gaps and evidence.

1.6. Main effects at European and national levels

The JPIAMR Strategic Research Agenda One Health approach, covering human and animal health as well as the environment, has had a **structural impact on the scientific community with crossfertilisation** among scientific areas by funding knowledge gaps and new types of projects/areas and by funding research and policy networks (new scientific links, open possibilities new networks). Combined with an **increased transnational collaboration and leverage of national funding** (for example Switzerland, Norway and Sweden), this approach attracted more researchers to the field. The SRA development process and other alignment activities have had impact at policy level by supporting the development of national AMR strategies and plans in most member countries. **Increased interoperability and building of trust** were added values of JPIAMR. All initiatives and tools of the JPIs are open to all and offer excellent scientific and science policy networks. Less research-intensive countries should be encouraged to use JPIs and other P2Ps as a stairway to excellence through collaboration.

Coordinating research priorities and calls with the EC, IMI and the pharma industry, through a specific working group with regular meetings and joint workshops has contributed to knowledge-exchange and enhanced strategic deliberations, with both industry and policy makers. JPIAMR is strategically engaged with future funding decisions by industry through its participation in the IMI2 Strategic Group on Infectious Diseases and the joint group EFPIA-IMI-EC-JPIAMR. It has also contributed to the international antibiotic pipeline by co-organising the first "Transatlantic Clinical Trials Workshop in the area of AMR" (January 2016) attended by regulators and pharma and an "Early antibiotic discovery workshop" (January 2017).

JPIAMR is now recognised as an **international research platform** extending beyond Europe. JPIAMR is engaging with international stakeholders, such as WHO, USA (through NIH and TATFAR with joint workshops), ASEAN (workshops and new call) and G7/G20 in the development of AMR statements. JPIAMR activities are included in the G7 and G20 AMR declarations, in the WHO AMR Global Action Plan and in the latest UN AMR resolution. We work closely with the European Commission and the general AMR policy level through being a key stakeholder in the implementation of the new EU AMR Action Plan, and more specifically with DG Research (definition of research priorities, research activities and international activities), and also with DG Santé with a new AMR Joint Action that will be instrumental in bringing about alignment of European health authorities. We have regular contacts on regulatory issues with the European Medicament Agency (EMA) and on surveillance with ECDC, through being part of the organisation of the European Antibiotic Awareness Day.

2. SWOT Analysis

The SWOT analysis is based on contributions from the JPIAMR Management Board and Scientific Advisory Board.

Strengths

JPIAMR is an AMR international research collaboration platform with strong links to the European Commission, the national governments of its member countries, and other international initiatives in its area. We have so far achieved a critical mass and have seized the political momentum to position ourselves as a major player combatting resistant bacteria by aligning and coordinating research through our Strategic Research Agenda and by facilitating and supporting research directly. Strong networks have been established with industry, with closer collaboration planned in the future. Through its activities, JPIAMR contributes to capacity-extension at a wider European level across xx countries. The broad One Health approach ensures a focus on the discovery phase of therapeutics, development of new biomarkers for diagnostics, and on preventing the transmission of resistant bacteria between humans, animals, and the environment.

Weaknesses

JPIAMR has a short operational time of only 5 years. In some member countries, the link between research coordination through JPIAMR and other national actors has not been established or is weak. This leads to a perceived competition between funding streams in the national research system and European programming, and sub-optimal coordination with national priority-setting in human and animal health policy work. National representation in JPIAMR is in some cases dominated by a single actor, occluding other perspectives from some member countries, such as parallel activities of relevance to low- and middle income countries, support for innovation or a One Health perspective. Like many other international cooperative efforts, JPIAMR is also hindered by national legislation and rules for research support (such as "virtual common pots").

Opportunities

JPIAMR is in an excellent position to bridge the gap between research and policy, by bringing together various national agencies and ministries to work towards a One Health strategy. It provides a forum for member countries to share best practice and to network with each other, with other international initiatives, and with industry. The JPIAMR platform is attractive to many global players, allowing JPIAMR to engage fully with countries with high AMR rates and to address research questions and challenges unattainable at national level. Joint coordination of priorities and actions should lead to increased efficiencies of scale and capacity extension within Europe and beyond. Global dissemination and uptake of results through JPIAMR's international communication strategy can support translation of science into innovation of products and policy development to stop the spread of resistance.

Threats

The importance of the AMR challenge has led to many international efforts being launched in a short timeframe. This may lead to similar approaches being used by other initiatives, which may diminish the role of JPIAMR and thus reduce the value added, and also duplicate efforts. National governments may also decide to discontinue their commitment to JPIAMR and to transnational engagement, and may prefer to develop alternative new funding instruments with a similar function to JPIAMR, if the political momentum changes direction. On the other hand, the popularity of JPIAMR could generate such an interest in participation by new countries that the JPI would become less flexible and bureaucratic, due to the increase in membership, if the governance structure is not transformed.

STRENGHTS	WEAKNESSES
-Unique international collaboration platform at	-Perceived competition between national –
governmental level	European programming; national focus more
- International role in multilateral funding	important
-One Health approach	-National representation in JPIAMR is
- Stronger interest of industry	sometimes partial, as responsibility for AMR
- Political momentum	and One Health is split between Health,
- Joint strategic research agenda aligning	Agriculture, and Research at national level,
national and international priorities	leading to lack of coordination
- Enables comparative multi-country studies to	-Classical approach with calls – no portfolio of
fill knowledge gaps	programme management
	- Lack of real common pot for funding
OPPORTUNITIES	THREATS
- Leading all the interests in the field/acts at	-Other international instruments building up
different levels; coordination capacity	with similar approaches; value added not
- Seen as a global funder (true funder of One	recognised; duplication of efforts
Health)	-Governance structure and complexity of
- Addressing neglected fields of AMR R&D not	procedures prevents action and inclusion of
yet covered	low-resource countries
- Bridging the gap between research and policy	
by bringing together different	
- Globalisation/joint forces: for many countries	
interested in going global, this is the platform to	
channel it	
- Facilitating access to resources and data	
between European countries and beyond	

Analysis and recommendation

AMR cannot be tackled by individual countries. Collaboration, alignment and communication are essential for success, especially between policymakers and science. This is a key main area where JPIAMR is ideally positioned and well connected to contribute.

Thus, JPIAMR should focus more on implementation and consolidation of knowledge, collaboration, networks and other results. The goal of JPIAMR should be to support policy makers around the world with success stories and action plans on AMR. Science-based evidence and examples of enthusiastic collaboration in the field will provide for a sustainable policy. The focus should move from biomedical research towards more attention on how research and available data can be translated into policies.

Another strength area of JPIAMR is the One Health approach, but JPIAMR itself needs to fully integrate the One Health perspective in all processes. This can be done by implementing the veterinary and environmental approach into the governance structure of JPIAMR.

When more countries join JPIAMR, the average JPIAMR policy will get a more diverse perspective. Countries outside the EU will face different challenges concerning AMR. Wealthier countries face different challenges than middle-income countries. This demands different policies and approaches on AMR. JPIAMR must adapt its governance structure to accommodate this, and could function as an inspiration and a bridge between these countries and their various challenges and approaches.

3. Vision, Future Major Goals and Objectives

3.1 Ambition and vision

The **vision** of JPIAMR by 2025 is to actively be:

"Turning the tide of AMR in Europe and beyond"

The JPIAMR mission for the next years (2020-2025) is:

"To join forces across nations by leading the alignment, coordination, and support to Antimicrobial Resistance One Health collaborative research and global policy activities"

JPIAMR's main aim for the next years (2020-2025) is:

"To provide new evidence and innovations that reduce the burden of antimicrobial resistance through coordinated global collaborative research in Europe and around the world."

The SRA, mission and vision highlights how JPIAMR would face the problem of AMR "by producing new research and creating networks that can create long-term momentum for other areas in society", by "providing scientific evidence" and "finding routes for novel antibiotics and new anti-infectious strategies".

All initiatives to control the problem at a global scale, including those highlighted as "urgently needed", demand the "... support of theoretical and applied research to better understand the origin, spread, evolution and development of resistance in microorganisms". This is what makes JPIAMR different from other bodies: to combat the challenges of identifying and exploring novel strategies/approaches and to add scientific evidence. The JPIAMR calls, workshops and SRA reflect the input of JPIAMR in searching for novel ways to approach the problems.

3.2 Major goals and objectives

The **goals** of JPIAMR are:

 To develop global AMR research strategies and programmes through alignment of national and international research programmes, by defining and implementing the JPIAMR Joint Strategic Research Agenda (SRA) and setting common (research) priorities in open consultation with the European Commission, WHO, TATFAR, G7/G20 public and animal health authorities, industry (such as EPFIA, BEAM Alliance), the scientific community, and other relevant stakeholders.

The short, medium and long term objectives of goal 1 are:

- By 2020, JPIAMR is continuing to establish inter-/intra-governmental platforms to align national and international initiatives on AMR research and drug discovery and development within the framework of UN, WHO, OECD, G7/G20 and EU.
- By 2020, the potential of European partnership in AMR research is realised by expanding JPIAMR membership to cover most European countries.
- By 2023, the EU (through its EU AMR Action plan) and all JPIAMR member states have developed national strategies and action plans that include research priorities aligned with the updated JPIAMR SRA of 2023.
- By 2025, international alignment of AMR research is further strengthened through inclusion of countries from all continents.

2. To **support and coordinate transformative research** through open, national and joint transnational competitive calls for proposals in strategic areas of AMR research, where efficiencies of scale can be achieved by avoiding duplication and fragmentation, promoting and pooling of AMR research resources and infrastructures, creating research networks and mobilising the best human talent (increasing scientific capacity).

The short, medium and long term objectives of goal 2 are:

- By 2020, the JPIAMR portfolio of funded research projects reaches a critical mass to enable cross-interaction between projects at the JPIAMR annual conference.
- By 2020, the JPIAMR database of AMR research funding, outputs, and infrastructures for promoting collaboration, use, and increased trans-national access is completed.
- By 2020, JPIAMR has joint transnational capacity programmes to mobilise researchers to enter the field of AMR research.
- By 2023, JPIAMR has joint transnational grant programmes in all relevant AMR research areas, with regular calls for proposals.
- By 2023, JPIAMR has supported a programme in collaboration with ESFRI and ERIC for increasing access to, use of, and collaboration between AMR research resources and infrastructures.
- 3. To support and coordinate the JPIAMR Virtual Research Institute (JPIAMR-VRI), a dynamic network of AMR research facilities, comprising a platform for scientific interaction between the member states, and a joint transnational research capacity in the area of AMR, providing close contact between JPIAMR and the scientific community.

The short, medium and long term objectives of goal 3 are:

- By 2020, the first network(s) of research institutions is/are established.
- By 2023, the JPIAMR prevention and interventions research network of hospitals and primary care institutions is operational, and will be complementing existing clinical trial networks initiatives.
- 4. To promote innovation and translation of research results into health care, health policy and animal health policy through a permanent dialogue with industry and its networks (such as BEAM Alliance), public-private partnerships (such as IMI), and relevant policy makers and managers.

The short, medium and long term objectives of goal 4 are:

- By 2020, JPIAMR serves as a bridge between pre-clinical science, and clinical and commercial developers of new treatments and diagnostics.
- By 2020, the JPIAMR database provides data on academic, SME and industry projects to facilitate the development of joint translational projects.
- By 2020, all JPIAMR research grant programmes encourage multi-disciplinary and translational approaches with a One Health perspective.
- By 2021, JPIAMR issues regular calls for proposals for joint public-private projects in areas of identified gaps and opportunities.
- By 2025, JPIAMR has established a portfolio of research outputs and results of potential value to related industries, health care institutions and public health decision-makers.

5. To **bridge the gap between research and policy** by collecting and sharing information on funded AMR research projects, research infrastructures, research output and impact with the scientific community and other relevant stakeholders.

The short, medium and long term objectives of goal 5 are:

- By 2020, the JPIAMR Database is established as the main information system across JPIAMR member countries for data on funded AMR research projects, research infrastructures, and research output and impact.
- By 2021, JPIAMR actively seek input from policy-makers for identification and definition of research priorities for updating the SRA and future joint activities.
- By 2021, JPIAMR publishes a biannual analysis of policy initiatives of relevance for scientists, knowledge gaps and unnecessary duplications within AMR research.
- By 2021, JPIAMR facilitates communication between the research community and policymakers by creating meetings for systematic interactions and publication of an annual report on different areas of AMR, summarising research outcomes and evidence-based findings.
- By 2022, JPIAMR includes industry representatives, policy makers, and other stakeholders in its expert panels.
- By 2023, JPIAMR has initiated a secondment/exchange program for AMR scientists/policymakers.

3.3 Expected impact

By achieving the stated objectives, the expected impact by 2025 is:

- Coordinated and aligned national and international public and private AMR research initiatives, where the JPIAMR SRA serves as a global guideline for prioritisation of investments in research, innovation, and infrastructure with a One Health One World perspective.
- Increased joint JPIAMR funding of research projects, mobility and training of researchers, and infrastructure, with a strong leverage effect on national AMR research budgets in Europe and beyond.
- Strengthening of the European Research Area by expanding the AMR research community networks to all European Union member states, supporting mobility, training, capacity building and facilitating access and use of infrastructures.
- Increased development of new drug candidates and alternatives to antibiotics, better diagnostics, and improved evidence-based measures to prevent the spread of AMR.
- Reduced knowledge gap between researchers, industry, and policymakers, thereby optimising
 prioritisation and funding of AMR research and innovation at national and international level.

4. Principles for implementation

4.1. Governance

By 2020, JPIAMR shall already have established strong networks vertically from the research community and funding agencies to national policy level and supranational initiatives, strategic discussion with industry, input from the public health sector and other stakeholders, thereby placing it in a unique position to integrate the global effort to tackle the challenge of AMR.

By 2020, possible scenarios for creating a long-term sustainable governance structure for JPIAMR will have been explored and the model supported by JPIAMR members will have been implemented. It will include a business plan for the sustained JPIAMR management and operation of long-term activities (such as leveraged funding for calls, maintaining knowledge hubs, supporting a virtual research institute and AMR project information resources).

The period 2020-2025 will be a consolidation period, where new global members will be offered different membership levels according to their needs and available resources.

4.2. Research and innovation activities

Proposed activities and instruments for the implementation of the goals and objectives:

To support and coordinate transformative research, JPIAMR will:

- Fund regular open national and joint transnational competitive calls for proposals in all strategic areas of AMR.
 - This includes calls for proposals for joint public-private projects, "bolt-on funding" to top up projects, exploiting synergies with calls of other funding instruments (such as IMI, GARD-DNDI).
- Support networking and partnership among research communities and create joint transnational capacity programmes to mobilise the best human talent, thereby increasing scientific capacity.
- Organise scoping workshops, strategic workshops, intergovernmental workshops, projects workshops, and an annual JPIAMR annual conference to support or develop calls or updates, and adapt prioritisation of the SRA.
- Maintain the JPIAMR database of AMR research and infrastructures to promote collaboration, use and increased trans-national access.
- Support a programme in collaboration with ESFRI and ERIC for increasing access to, use of, and collaboration between AMR research resources and infrastructures.

To support and coordinate the JPIAMR Virtual Research Institute (JPIAMR-VRI), JPIAMR will:

- Coordinate and support JPIAMR-VRI, a dynamic network of AMR research facilities comprising a platform for scientific interaction between member states, and a joint transnational research capacity in the area of AMR.
- Support the development of the JPIAMR prevention and intervention research network of hospitals and primary care institutions.

To promote innovation and translation of research results, JPIAMR will:

- Update and promote the JPIAMR Strategic Research Agenda (SRA).
- Fund regular open national and joint transnational competitive calls for joint publicprivate projects in areas of identified gaps and opportunities, encouraging multidisciplinary and translational approaches with a One Health perspective.
- Serve as a bridge between pre-clinical science, and clinical and commercial developers of new treatments and diagnostics through a permanent dialogue with health care, health

- policy and animal health policy, industry and their networks (such as the BEAM Alliance), public-private partnerships (such as IMI) and relevant policy makers and managers.
- Facilitate researcher mobility between academia and industry by organising fellowships programmes, summer schools, exchange and training programmes, and industry PhD awards.
- Provide data on academic, SME and industry projects, and a portfolio of AMR research outputs and results for related industries, health care institutions and public health decision-makers, to facilitate development of joint translational projects.

4.3. Alignment

Proposed activities and instruments for the implementation of the goals and objectives:

To develop global AMR research strategies and programmes through the alignment of national and international research programmes, JPIAMR will:

- Develop the governance model, international strategy, and membership policy, to make JPIAMR's operations adapted to an increased membership of most European countries and major middle-income countries globally.
- Facilitate and support the development of national strategies and action plans that include research priorities aligned with the updated JPIAMR SRA in all member countries.
- Influence and align international and intergovernmental AMR research initiatives, by developing a joint JPIAMR member state approach and position on strategic issues.
- Coordinate JPIAMR member state alignment with the activities and initiatives of the next EC Framework Programme and other EU initiatives.

To bridge the gap between research and policy, JPIAMR will:

- Organise strategic workshops to map the AMR landscape (for example funding, policies, infrastructures) and discover the opportunities for harmonisation.
- Include industry representatives, policymakers, and other stakeholders in JPIAMR's expert panels.
- Initiate an exchange/secondment programme for AMR scientists/policymakers.
- Collect and share information on funded AMR research projects, research infrastructures, research output and impact with the scientific community and other relevant stakeholders through the JPIAMR database and workshops, to facilitate communication between the research community and policy makers.
- Publish a biannual analysis of policy initiatives of relevance to scientists, knowledge gaps and unnecessary duplications within AMR research.
- Publish an annual for policymakers on AMR research.

4.4. Outreach activities

In order to maximise the impact of JPIAMR, the results and knowledge of the funded research projects and additional activities generated by JPIAMR will be disseminated widely within the scientific community, as well as to a full range of potential users and uses beyond research, including commercial, investment, social, environmental, policy making, standard-setting, skills and educational training. JPIAMR will facilitate dissemination through its ongoing contacts and networking with industry and policy makers, and will help to segment the target audiences and to tailor the message appropriately. A network of JPIAMR member communication capacities and staff will be initiated by 2017/18. JPIAMR is deploying 21st century communication capacities to share and engage audiences and stakeholders on an international/global scale, embracing fragmented communications capabilities.

Intellectual property rights issues - exploitation of results

JPIAMR will not by itself generate knowledge that needs to be protected. Therefore, no intellectual property (IP) management is needed. However, the handling of IP within the funded research consortia will be part of a consortium agreement to be signed by all research project partners, which will follow the JPIAMR IP guidelines, as well as its open access and monitoring policy.

Dissemination activities

JPIAMR will provide information materials, online and offline resources and infrastructure for dissemination of information and ensure increased awareness of the JPIAMR calls, supported projects, and other activities, which will facilitate stakeholder engagement and participation.

JPIAMR will develop promotional and marketing material to support internationalisation activities in particular, by branding the benefits and advantages of joining JPIAMR. A network of communicators among the participating agencies will be established to facilitate dissemination and communication.

Various JPIAMR social media, online tools and channels, including the JPIAMR website (http://www.jpiamr.eu/) are available to disseminate relevant information to relevant groups in order to facilitate knowledge transfer, including press releases, website "news" items, Twitter feeds, newsletters, videos, webinars, as well as group emails forwarded via the JPIAMR stakeholder database (contact details of more than 1500 individual stakeholders).

4.5. Monitoring and evaluation

JPIAMR has had a monitoring and evaluation framework since 2013. Implementation of this policy is regular with monitoring and ex post evaluation of the funded projects (outputs and impacts), as well as self-evaluation of JPIAMR as an initiative. We also have a database of funded projects (at joint, national and EU level).

http://www.jpiamr.eu/activities/evaluation-framework/

During 2017, all the JPIs are together developing a set of joint impact indicators that will be included in our evaluation exercises.

4.6. Relations with other initiatives and programmes

Synergies with other JPIs, EC Framework Programmes, structural funds, and/or other international organisations

JPIAMR's long-term strategy will lead to the following synergies, and are continuously built up in the already established ones:

- JPIAMR will be able to act as implementer of key research aspects of the new EU AMR Action
 Plan, through continuous dialogue on thematic coordination with the European Commission
 DG Research, as well as DG Sante.
- JPIAMR will continue to facilitate coordination and translation of research and innovation through participation in the joint working group led by the European Commission DG Research Health "EC-JPIAMR-IMI-EPFIA", with the IMI specific programme on AMR (NDBB) and major pharmaceutical industry as well as SMEs (BEAM alliance). This group aligns future calls among the different programmes in the area of AMR. The group is key to defining key complementary actions together with industry. DG Sante, ECDC and DG Sante are also participating in these meetings.

- JPIAMR will continue to strengthen the One Health perspective of joint AMR research through
 regular exchange with the main complementary European Initiatives (EJP MEDVET on
 zoonosis-AMR, DG Sante Joint Action in AMR), European agencies (EMA and ECDC), and with
 key stakeholders, such as the European Veterinarian and Clinical Microbiologist and Infectious
 Medicine Associations.
- JPIAMR will **support widening** of the ERA by jointly exploring synergies and collaboration with the EU together with the other 10 JPI chairs. One of the priorities for the future is to link with structural funds. Efforts are jointly made with 10 JPI chairs to improve this connection.
- JPIAMR will support alignment, coordination, and/or cooperation between or with other international AMR Initiatives (WHO, G7/G20, TATFAR, GARD/DNDI and private fund providers, such as Wellcome), through continuous dialogue and participation as a member or observer in strategic meetings.
- JPIAMR will continue to have regular exchanges with all JPI chairs and secretariats (JPI chairs meetings) and with the GPC, in any activity directed at raising the profile of JPIs in the European research context. We are particularly interested in the relationship between and prioritysetting of national programmes and JPIs, which is a common issue for all JPIs.
 - JPIAMR will share experiences and challenges with other JPIs in the health area (for example JPND and HDHL), where collaboration exists in the evaluation of tools for monitoring and assessing the impact of research.
 - JPIAMR could achieve synergies with JPI Water, which has launched a call on water pollution with projects funded in the area of AMR and environmental aspects of AMR transmission. A potential joint call in 2020 is under exploration. Likewise, HDHL has interests in food-borne diseases and water pollution, which links to the use of antibiotics in food production. This could also be a topic for a joint call.

5. Sustainability Requirements

Financial perspectives

JPIAMR's long-term strategic plan for 2020-2025 describes an ambitious expansion of JPIAMR's activities in several domains. The scientific and societal challenge of AMR is likely to increase over the next ten years, and JPIAMR's strategy is based on the following three main assumptions:

- The present member countries will continue to prioritise AMR research at the same or higher level.
- Additional countries, within and outside Europe, will recognise JPIAMR as the main collaborative AMR research effort.
- The strong partnership between JPIAMR and the European Commission will continue, with alignment of activities between member countries and the next framework programme, including long-term EC support for JPIAMR's key coordinating operations.

To ensure the long-term sustainability of JPIAMR, a new sustainability model with associated business plan is being developed and will be put in place by 2020. The financial support will build on a combination of:

- Membership fees (flexible membership fee structure adapted to the engagement and income level of individual countries).
- Members' voluntary contributions to cover activities and secondments to the secretariat.
- EC support for coordination costs and enabling inclusion of low-income European countries.

The latter is seen as a necessity by all JPIs to be accommodated within the future Framework Programme by the European Commission.

Presently, coordination costs are mainly attributed to the **JPIAMR Central Secretariat**, set up in 2012 and hosted by the Swedish Research Council. It is responsible for the day-to-day management of JPIAMR's activities and ensures the necessary logistical coordination and communication between JPIAMR members and governance bodies, and international partners.

The central staff of 5 FTEs (in 2017) and activities of task-specific working groups, led by different member countries in a **Distributed Secretariat/Coordination Model**, are funded in a mixed model with fees (in 2016) and contributions in kind from members (including personnel), combined with EC support in the form of a Coordination and Support Action until 2020.

JPIAMR member countries will mobilise **national funding for all scientific activities and joint calls**. JPIAMR members have committed on average 15 million EUR per year (range 11-23) so far in five joint calls, with a trend of increasing budgets and larger number of participating countries. The implementation plan includes at least one new joint call every year, with a budget forecast between the level of current calls (minimum scenario) and an increase of 5 % (maximum scenario). Participation in annual scientific workshops and policy meetings, as well as the costs for management, board and steering committee meetings, are also funded in kind by the member countries. An ERA-Net co-fund action awarded in 2015 will however, support the management of the joint calls until 2020.

EC financial support for key coordination activities is necessary in order to:

- Support a true European Virtual Research Institute.
- Strengthen intra-Europe cooperation, incentivising countries to get on board, increase inclusion level of European countries, support the increase of research capacity in widening countries (the introduction of higher fees might leave some countries outside).
- Increase engagement with industry collaboration (bridging the gap between industry and academia).
- Enhance globalisation and interaction with countries outside Europe. It will provide greater impact and build further capacity. JPIs as visible entry point to Europe.
- Support sustainable and continuous alignment of research programmes among national programmes and also with the 9FP.

A new, long-term JPI-adapted support action instrument, replacing but building on the current CSA instrument, is needed to ensure participation from the whole ERA. We strongly support a new multilateral funding instrument or adaptation of existing instruments to develop sustainable long-term partnerships and agreements within and beyond H2020.

The current ERA-Net co-fund model carries too high an administrative burden for a small EC co-funded budget in a single joint call, making it of less importance. A multi-call arrangement and administrative simplification would be welcome. Modification of the rules to enable use of structural funds for research activities would be helpful.

The JPIAMR Virtual Research Institute will become an important European AMR resource and would benefit from EC support (an EJP could be a potential instrument to fund this initiative, focusing on coordination of research-performing organisations).

JPIAMR forecast of expected budget per year:

OF MEMBERS' CONTRIBUTI				
Activity title	Effort	Personnel	Description of expenses	Cost EUR
Support & coordination of research	1.5	0.5 FTE central; 1 FTE in kind	Calls management, experts meetings, database, scientific workshops (2 x 36K) in kind	130 000
Virtual Research Institute (VRI)	1.5	0.5 FTE central; 1 FTE in kind	Central networking budget per VRI pillar (6 x 50K)	300 000
Promote innovation & translation	1.5	0.5 FTE central; 1 FTE in kind	Meetings	5 000
Research programmes alignment	1.5	0.5 FTE central; 1 FTE in kind	Meetings in kind	0.00
Policy alignment	1.5	0.5 FTE central; 1 FTE in kind	Meetings in kind	0.00
Internationalisation & evaluation activities	1.5	0.5 FTE central; 1 FTE in kind	Databases, surveys	30 000
	9.0		3 FTE central	240 000
			6 FTE in kind	0.00
TOTAL				678 000 EUR
TOTAL (without the VRI)				378 000 EUR
OPERATIONAL CENTRAL R	ESOURCE	ES PER YEAR		
Activity title	Effort	Personnel	Description of expenses	Cost EUR
Mix-model central secretariat	1.0	Head secretariat	Travel budget	10 000.00
model combination cash budget and members in kind	1.0	Scientific coordination	Governance meetings:	
contributions: coordination and	0.5	Finance/admin	SAB meetings (2 x 11 500)	23 000.00
governance	0.5	Communications	SC meetings in kind (3 meetings)	0.00
	1.0	Steering committee Mbs in kind	Strategic workshops	18 000.00
			MB meetings in kind (2 meetings)	0.00
			Communications, Web & admin costs	15 000.00
	4,0		3 FTE central	300 000
			1 FTE in kind	0.00
				366 000 EUR
TOTAL EXPENSES per year				1 044 000 EUR
				744 000

6. Significant Risks and Associated Contingency Plan

6.1. Significant risks

The associated risks are financial and organisational:

- Insufficient funding and support of JPIAMR from member countries due to budget cuts or a shift in political support or priorities towards national programmes, or alternative international initiatives.
- Insufficient support from the European Commission.
- Diverse membership leading to poor governance. When more countries join JPIAMR from outside Europe, the average JPIAMR policy will get a more diverse perspective. This demands different policies and approaches on AMR, but also puts pressure on the JPIAMR governance model to accommodate and adapt to rapid changes.
- Rapid growth of JPIAMR activities may lead to poor implementation and focus. The long-term strategy of 2020-2025 includes many new ambitious activities. The risk is that not all member countries are prepared or able to support all new JPIAMR actions, thus reducing their effect. The need for stronger central coordination requires new organisational skills and many new processes and procedures to be implemented.

6.2. Contingency plan

The risks associated with the long-term strategy are linked to each other. Reduced funding and support will lead to less ability to implement actions and vice versa. The contingency plan identifies two different alternative scenarios B and C from scenario A, which is the plan based on the long-term strategy.

Scenario B: Reduced financial support from EC

- Increase membership fees
- Adapt membership and governance
- Reduce level of activities
- Seek volunteer members to cover activities in kind
- Reduce structure of the secretariat and seek secondments
- Seek alternative sources of funding for the Virtual Research Institute by in kind contributions

Scenario C: Reduced financial support from member countries

- Adapt membership and governance
- Develop a core group of members that provides leadership and execution
- Refocus activities in more policy areas