# The Global Antimicrobial Resistance Research and Development Hub

Evidence-based decision making for AMR R&D

# 1. Foreword

What would happen if the drugs didn't work and the medicine cabinet was bare? This is not a thought experiment. This is a reality for 1.27 million people globally who died as a direct result of a drug resistant infection in 2019 – one in five of those deaths was a child under five years of age. This is a reality that is set to push an additional 28 million people into extreme poverty and cost governments a further 1 trillion US dollars in health care costs by 2050 if no action is taken. We can't stop antimicrobial resistance (AMR), but we can slow its progression, mitigate its devastating impacts and be better prepared to prevent and respond. Research is at the core of this response. But with finite resources and funds, and in the face of many ongoing global challenges, efforts need to be

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UA Globale Gesundheit
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better co-ordinated and allgned to ensure the most critical health needs are addressed. Since inception, the Global AMR R&D Hub (hereafter 'Hub') has been working to maximise the impact of existing and new research to mitigate AMR, by offering a unique evidence base to enhance AMR research and development (R&D) activities and policies across the One Health spectrum, and acting as a bridge between organisations, funders, regions and sectors. As we look to the future and with your support we will accelerate, consolidate and strengthen our activities to foster a shared agenda and oversight for AMR R&D that will ensure the products, tools and strategies with the highest potential societal impact are developed and available to those who need them.

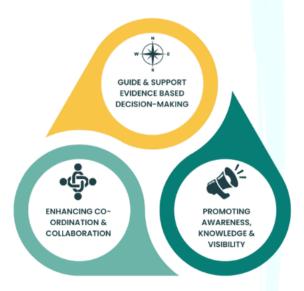
# 2. Our Vision & Mission

#### **Our Vision**

A sustainable ecosystem for R&D of the solutions, tools, products and strategies we need to mitigate the ongoing impacts of AMR

## **Our Mission**

We provide an evidence base to enhance AMR R&D activities and policies across the One Health spectrum



# **Key objectives**

- Inform high-level decision makers on R&D pipelines and other relevant aspects of AMR R&D, in order to identify and prioritise R&D gaps and help focus high-level decision-making,
- Facilitate the efficient allocation of resources,
- Promote increased investments into push and pull incentives for AMR R&D in order to maximize the impact of national and international research activities,
- Foster international research collaboration among different partners globally, including industry and academia,
- Support the filling of product pipelines with priority candidates, using an appropriate mix of incentives, with a view to the development of deployable products, while recognising the importance of access, prudent use, and stewardship,
- Inform policy makers on AMR R&D and keep attention on AMR at high political levels,
- Raise and maintain public awareness and visibility through communication of the work of the Hub and its results.
- Build a global AMR One Health R&D community.

### **Our Approach**

The combination of a strong data foundation with a unique global platform for exchange of information, offers the potential for co-creation of solutions for AMR across the push and pull spectrum

Dem Ausschuss ist das vorliegende Dokument in nicht barrierefreier Form zugeleitet worden.

# 3. Our History

Following the adoption of the 'Global Action Plan on Antimicrobial Resistance' in 2015, reiterated by the publication of 'The Review on Antimicrobial Resistance' in 2016, there was a growing awareness of the need for increased coordination of investments in AMR R&D to help prioritise the development of the products, tools and strategies with the highest potential societal impact. Recognising the necessity to prevent overlaps and duplicative efforts in AMR R&D given limited resources and finite funds, a call was made by G20 leaders in 2017 for the establishment of a new international R&D collaboration Hub. The Hub was launched in May 2018 during the World Health Assembly (WHA) and commenced operations in January 2019, with the establishment of a dedicated Secretariat in Berlin to oversee administrative planning and implementation.

"We call for a new international R&D Collaboration Hub to maximise the impact of existing and new antimicrobial basic and clinical research initiatives as well as product development."

G20 Germany 2017 G20 Leaders' Declaration: Shaping an interconnected world, Hamburg 7-8<sup>th</sup> July 2017

## 4. Governance & Resources

The Hub is governed by a Board of Members as the key decision-making body, with five Observers. The Board of Members is supported by a lean Secretariat, as well as a Stakeholder Group consisting of 20 organisations from academia, industry, research funders and civil society.

- Board Members: Australia, Brazil, Canada, China, European Commission, France, Germany, India, Italy, Japan, The Netherlands, Norway, Russia, South Africa, Spain, Sweden, Switzerland, Türkiye, United Kingdom, United States of America, Bill & Melinda Gates Foundation, Wellcome Trust
- Observers: Africa Centre for Disease Control (Africa CDC), Food and Agriculture Organization of the United Nations
  (FAO), Organisation for Economic Co-operation and Development (OECD), World Health Organization (WHO), World
  Organisation for Animal Health (WOAH)
- Secretariat: 5x full time staff based in Berlin, Germany under the administrative umbrella of the German Centre for Infection Research (DZIF)
- Funding: Grant funding from the German Government 2019-2024
  - o 2019 2021: Federal Ministry for Education & Research; Ministry of Health
  - o 2022 2024: Federal Ministry for Education & Research



# 5. Progress & Key Achievements

Since its inception in 2018, the Hub has worked towards its mandate of improving coordination of international efforts and initiatives to tackle AMR, by building a unique foundation of knowledge on AMR R&D and encouraging collaboration and knowledge sharing across the push and pull spectrum via working groups, engagement of members and publication of knowledge reports and policy briefs. In tandem, the Hub has worked to increase the visibility of and accelerate action on AMR R&D through advocacy at the highest political levels, including at the G20 and G7.

### 5.1 Establishment of a Unique Global Knowledge Centre for AMR R&D

- <u>Dynamic Dashboard</u> March 2020: An online database of public and philanthropic funding (since 2017) and current initiatives in AMR R&D. It is the most comprehensive source of information on AMR R&D available globally and is designed to synthesize and inform the global landscape of AMR R&D efforts, providing a key resource for stakeholders across the AMR spectrum, from researchers and policymakers to healthcare professionals and funding organisations covering all human, animal, plant and environmental sectors. By aggregating, visualising, and analysing data from initiatives worldwide, the Dashboard reveals trends, identifies gaps, and uncovers opportunities within the AMR research domain, serving as a cornerstone for strategic planning and resource allocation.
  - o Investment Gallery we have information on over 14,800 projects worth ~12.8 billion USD from 251 funders worldwide across all One Health sectors – human, animal, environment and plant. Since 2022, includes a Cross-Sectoral Report (projects involving more than one sector) and a Social Sciences Report is planned for Q1 2024.
  - Pipeline Gallery displays the WHO analyses of the antibacterial clinical pipelines (therapeutics & vaccines)

Screenshot of the Dynamic Dashboard, showing the Investments Gallery as at 19<sup>th</sup> February 2024

- Incentives Gallery summarizes push and pull incentives available worldwide for the development of new antibacterials
- Analysis Reports & Factsheets on historical funding trends were published in 2020, 2021 and in progress for 2024. Spotlight analyses on R&D funding for animal health vaccines, animal health in low and middle income countries and fungal pathogens were published in 2021 and 2022

### 5.2 Supporting Collective and Co-ordinated Action Across the Push & Pull Spectrum

- Establishment of a Pull Incentives Working Group 2022: Focused on the valuation of antimicrobials, nine working group sessions have taken place between 2022 and 2024 comprising the Hub's members, technical representatives and invited experts. Presentations and discussions on existing and planned incentives models, including from Canada, United Kingdom, Sweden, Germany, European Union and Japan as well as on topics such as the Transfer Exclusivity Extension Model and a Pan EU model. The working group is a unique space for discussions on shaping and implementing market shaping incentives for novel antibiotics.
  - Publication of a <u>Market Incentives Guide</u> (2023) in collaboration with Norway for policy makers and engagement with key stakeholders to gain further perspectives, resulting in <u>A shared dialogue on Pull Incentives</u> (2023)
- Establishment of the AMR One Health Working Group –
   2024: Building on information on investments in cross sectoral AMR R&D in the Dynamic Dashboard and using recent developments in the field such as the <a href="Quadripartite's One Health Priority Research Agenda for AMR">Quadripartite's One Health Priority Research Agenda for AMR</a>, the AMR One Health Working Group represents a platform for interaction, sharing perspectives across funders and ministries to further support implementation of One Health research and defining specific needs and ways of working.
- Active engagement in the Quadripartite's AMR
   Multistakeholder Partnership Platform: The Hub is co-lead
   of two action groups focused on (i) Mobilising resources in
   AMR for LMICs and (ii) Stewardship across the value chain,
   and is an active member of other action groups focused on
   the development of and access to new antibacterials,

as well as shaping recommendations for the United Nations General Assembly (UNGA) High-Level Meeting (HLM) on AMR in September 2024.

#### **PUSH & PULL INCENTIVES?**

Push Incentives are government or regulatory interventions which support R&D by directly lowering the costs of development. These tools are inputbased. Examples include research funding grants, contracts, public and private partnerships and tax incentives.

Pull incentives are policy tools to reward the successful development of a product by increasing or ensuring future revenue. Can be achieved through market-making (financial) tools or market-shaping (regulatory policies) rewards. Examples include, subscription models, revenue guarantees which de-link revenues from volumes sold, higher reimbursement and market entry rewards.

### 5.3 Provision of Evidence on Incentives to Guide Decision-making on AMR at the Highest Political Levels

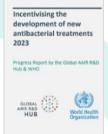
- Landmark analyses of national policy tools and market potential of new antibiotics and diagnostics: Following a call from the G20 Japan Presidency to the Hub in 2019 to analyse push and pull mechanisms for AMR R&D, the Hub established an Expert Advisory Group and three key studies and associated policy briefs were published in 2020 and 2021 that explored the challenges inhibiting more unified and co-ordinated global action. These landmark studies provided insight into policy makers perspectives on incentives, key guidance on national policy tools and levers for supporting the development of the most needed antibiotics and diagnostics as well as quantitative data on the scale of the market challenges. The findings continue to support current thinking on market intervention and highlighted the need for delinkage of sales from volume and co-ordinated action on incentives.
- Delivery of G7 requested progress reports on incentivising the development of new antibacterials: Initiated by a G7 request in 2021, the Hub in collaboration with WHO delivered two progress reports to G7 Finance & Health

- Ministers in 2022 and 2023 to help support deliberations regarding activities countries are taking to incentivise the development of antimicrobials. These reports highlighted the need to stimulate R&D whilst considering equitable access to new antimicrobials addressing the most critical public health needs.
- Recommendations to the G20 on AMR R&D based on the Dashboard and other analyses in 2020, 2021 & 2023. In 2022 and 2023, the Hub advocated the need to consider the development of AMR R&D targets for the development of - and equitable access to - antibacterials, vaccines and diagnostics addressing unmet public health needs.
- Provision of evidence on AMR R&D to the Global Leaders Group on AMR (2023) and in follow up expert consultation on the antibiotic development and access crisis (2023).

Example Reports & Policy Briefs (see www.globalamrhub.org)



2021: **Estimating Global** Patient Needs & **Market Potential** for Priority Health **Technologies** addressing AMR



2022, 2023: **G7** Requested **Progress Report** on Incentivising the development of antibacterials



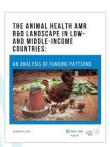
2023: Which economic pull incentive may be right for your country?



2021: The Global AMR R&D **Funding** Landscape



2021: Gaps & opportunities for development to veterinary vaccines to reduce use of antibiotics



2021: The Animal Health AMR **R&D** Landscape in LMICSanalysis of funding patterns

- The Hub participates in and host sessions at numerous conferences, workshops and webinars, including at events hosted by the G20, the High Level Ministerial Meetings on AMR, Global Leaders Group, Quadripartite, World AMR Congress, World Health Summit, Centre for Science and Environment, European Health Forum Gastein, and the One Health European Joint Programme.
- The Hub publishes a variety of articles and opinion pieces sharing evidence and perspectives on AMR R&D across the One Health spectrum, e.g. One Health Lens for AMR R&D funding (OMICS Journal), AMR R&D needs greater push through policies (Down To Earth, CSE) & A Global Hub supporting research into AMR (The Guardian, supplement), Impact of AMR on Cancer Care (AMR Control), and is called upon by news agencies and outlets to provide expert opinion (Deutsche Welle, 2023; Financial Times 2021, 2022).

Our Newsletter (launched in 2020) and AMR Snapshots interview series (launched in 2021) keep AMR in the policy forefront and provide accessible insights on country AMR perspectives. Our interview series has featured experts such as the UK Special Envoy on AMR Dame Sally Davies, and Sweden's Ambassador for AMR, Dr. Malin Grape.

# The Hub in 2023?



# 6. Impact

- The Dynamic Dashboard a unique online repository of information on the global landscape of AMR R&D funding and incentives - has become a go-to resource for an ever growing number of countries and institutions worldwide, providing strategic insights, empowering global stakeholders to set priorities and maximise the impact of resources against AMR
- Resulting analyses of the Dashboard data (both in house and in partnership) have provided the first comprehensive insights into the funding landscape for AMR R&D globally, enabling identification of research funding gaps and opportunities across all One Health sectors
- The Hub-WHO progress reports requested by the G7 were the first to chart and benchmark relevant activities countries were undertaking to incentivise the development of new antibacterials and ensure access. The reports were discussed during Health and Finance Ministers meetings in Germany (2022) and Japan (2023), and featured key

- recommendations to shape thinking and action across the push and pull spectrum
- The outcomes of the Hub's studies on national policy tools for market potential following the development of new antibiotics and diagnostics to address the most pressing public health needs in AMR – the first to provide robust quantitative data on this topic – are helping to inform policy makers of the scale of the AMR R&D funding challenge and support current thinking on market interventions and incentives
- Our studies on market incentives have triggered the formation of a Hub working group on pull incentives to share and exchange information across countries and to link ministries and global actors
- The value of the Hub's evidence and work to foster cooperation and collaboration continues to guide thinking, shape policy and has been acknowledged at the highest political levels, including at the G20 and G7

#### Specific country/organisation examples (non-exhaustive):

- Dynamic Dashboard data and Hub consultations have provided the basis for the development of national AMR funding schemes and strategies for the German Government, the Public Health Agency of Canada and the Dutch Research Council (NWO)
- The Hub's publications have been used extensively, including in reports by the **Australian Government** Commonwealth Scientific and Industrial Research Organisation, the **European Commission Health Emergency Preparedness and** Response Directorate (DG HERA), the **Organisation for Economic Cooperation and Development** (OECD), the Wellcome Trust and the **World Organisation for Animal Health** (WOAH), and others
- The Hub is in consultation with the **United Kingdom Department of** Health and Social Care and the **Italian Ministry of Health** for a gap analysis of the current AMR R&D landscape

- Observer on WHO AMR advisory groups (e.g. R&D of Antibacterial Agents, Fungal Pathogens Priority List): Stakeholder member of the EC AMR One Health Network. **European and Developing Countries Clinical Trials Partnership 3** (EDCTP3) and EU-JAMRAI 2
- Numerous organisations consult & use the Hub's data to identify specific funding gaps, e.g. STAR-IDAZ **International Research Consortium** on Animal Health (IRC). Fleming **Fund. Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator** (CARB-X), Global Antibiotic **Research & Development** Partnership (GARDP), Joint **Programming Initiative on AMR** (JPIAMR), International Vaccines Institute (IVI), Global Coalition on Ageing (GCOA), International **Federation of Pharmaceutical Manufacturers & Associations** (IFPMA) and the BEAM Alliance
- Analysis of AMR R&D funding for animal health in LMICs with the **International Development** Research Centre (IDRC); Analysis of the impact of AMR R&D funding in LMICs with the International Centre for AMR Solutions (ICARS)
- Engagement of civil society, including the European Patients Forum, World Farmers Organisation (WFP) and Access to Medicine Foundation as part of the Hub's Stakeholder Group
- Engagement of student voices, through collaborations (formal and informal) with the PAR Foundation, Students Against Superbugs Africa, **Future Leaders Against AMR &** hosting students from Maastricht University in the Netherlands for virtual internships
- Hosting a staff secondment from the **Swiss Federal Office of Public Health**



"The Hub's data and analyses were instrumental in shaping the R&D aspects of the German National Action Plan on AMR"

Andrea Spelberg, Head of Division, Global and Public Health Research; Environment and Health, Federal Ministry of Education and Research, Germany

"Global AMR R&D Hub data and collaboration was key in informing Canada's rationale for an incentive pilot"

Joël Denis, Vice Chair of the Global AMR R&D Hub & Director General for Vaccines And Therapeutic Readiness, Public Health Agency of Canada



"We engaged the Hub Secretariat to determine which research lines would best complement the ongoing international effort in this space. I encourage other public funders to follow this approach"

Dr. Jasper Claesson, Dept of Pharmaceutical Affairs and Medical Technology, Dutch Ministry of Health, Welfare and Sport



"The Quadripartite organizations joined forces to develop a One Health Priority Research Agenda on AMR and the Hub is ideally placed to provide evidence and support its implementation"

Dr. Elisabeth Erlacher-Vindel, Senior Advisor AMR, World Organisation for Animal Health

# 7. Challenges in the AMR Policy Space

## Key challenges in AMR R&D at the present moment include:

- Lack of shared agenda and oversight for AMR R&D to meet priority needs
- Lack of long term vision in AMR R&D funding
- Lack of diversity in funding streams for AMR R&D, specifically related to LMICs across One Health sectors
- Lack of collective action on incentives for the development of new antimicrobials, vaccines and diagnostics
- Lack of collective approach to ensure access to priority antimicrobials, vaccines and diagnostics
- Lack of transparency on private investment data: data available are aggregated and not project-specific

# 8. Opportunities

Through its resources and mandate the Hub is uniquely placed to help address these challenges. The Hub offers a wealth of opportunities to contribute meaningfully to solving the shared problems of AMR. Members of the Board and its Observers, as well as the Stakeholder Group, benefit from shared knowledge and expertise, facilitating the exchange of best practices and innovative solutions. They gain access to data-sharing platforms and research insights that enable more effective surveillance, monitoring, and analysis of AMR R&D funding trends. Countries can amplify their impact on the global stage, influencing policy agendas, driving investment in AMR R&D, and shaping international collaborations.

### **Key Hub resources:**

- Dynamic Dashboard a unique and comprehensive database of AMR R&D investments and incentives
- Diverse reach of Board Members, Observers and Stakeholders across sectors, countries, and regions
- Platform for exchange of information and cocreation of solutions across the push and pull spectrum
- Reputation as a credible and neutral knowledge broker and provider

## The Hub is uniquely placed to use these resources to:

- Build partnerships and enhance collaboration on a global level and across regions and sectors
- Work towards a shared agenda, end-to end strategic coordination and oversight of AMR R&D
- Strengthen and accelerate action on AMR across the push and pull spectrum
- Provide evidence on AMR R&D and market incentives for global health governance structures and national governments
- Monitor progress in incentivising the development of and access to the most needed new health technologies addressing critical needs in AMR and encourage transparency of approach
- Foster collaboration between sectors and build a One Health Research community

## 9. The Future

We are at a turning point in which transformative change for action against AMR is visible on the horizon. 2024 represents a crucial year for AMR – fora such as the G20, the G7, UNGA's HLM on AMR in September and the 4<sup>th</sup> Global High Level Ministerial Meeting on AMR in November are pivotal chances to shape the AMR agenda – and in doing so its impact on global health for the next decade. Using our unique resources, and with a One Health approach, the Hub provides a credible source of knowledge and actionable evidence to help guide decision-making for AMR R&D and forms a platform for information exchange, enhanced collaboration and co-creation of solutions.

#### **Key Focus Areas:**

#### Actionable Evidence:

- The Hub continues to expand and optimise the main global data source on AMR R&D, the **Dynamic Dashboard** to provide the evidence base funders and policy makers need to help guide investment in AMR R&D
- The focus will pivot to gaining deeper insight on funding trends and the impact of funding across sectors to provide actionable evidence, including for the to be established Independent Panel on Evidence for Action on AMR

#### • Push Incentives:

- We have the evidence base to strengthen the AMR R&D ecosystem and promote co-ordination and collaboration
- We can support the establishment of AMR R&D targets to address priority public health needs, offering a platform for monitoring progress towards their attainment

#### Pull Incentives:

- We are strengthening our work on pull incentives to deliver a platform that can support alignment of individual pull incentives globally and promote collective action
- We can support accelerated action, track progress and assess effectiveness, whilst encouraging transparency and exchange of lessons learned

#### Access:

o The Hub is placed to be a bridge between countries and organisations to facilitate progress in this area, linking the AMR R&D agenda with the agenda for equitable access to and stewardship of new and existing priority antibacterials as well as AMR diagnostics and vaccines

### One Health:

 One Health continues to be at the core of what we do. Building on our existing activities and knowledge reports, we will leverage the Hub's AMR One Health working group and the Quadripartite's One Health Priority R&D Agenda for AMR to support implementation of One Health research globally

# **Contact Us**



www.globalamrhub.org



www.dashboard.globalamrhub.org



globalamrhub@dzif.de



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