

Translating AMR R&D mapping into
policy and action

GLOBAL
AMR R&D
HUB



Virtual conference – 2 December 2020

Conference Report and Recommendations

Aim

The first conference held by the Global AMR R&D Hub started the discussions to inform how the Global AMR R&D Hub, using its Dynamic Dashboard, can support the AMR R&D needs in the different regions and countries, by highlighting gaps that need to be filled and helping to identify collaboration or partnership opportunities.

Format

The conference was held virtually on 2 December 2020 over three sessions, each with a different focus area

- **Session 1** – identifying research gaps – Asia Pacific (One Health)
- **Session 2** – how are countries and organisations filling research gaps – animal health
- **Session 3** – partnership models – products and access (human health)

Recommendations

Please note that not all recommendations provided are within the remit of the Global AMR R&D Hub and may be referred to other international organisations that are better placed to consider. This will be outlined in the responses to the recommendations from the Global AMR R&D Hub's Board of Members.

- ❖ Establish strong global or regional thematic platforms/networks of research groups that have a common agenda and goal
- ❖ Develop policy white papers that outlines the global AMR R&D gaps and solutions and that present a global consensus (common voice).
- ❖ Develop a matchmaking database that lists researchers and research groups and their areas of expertise and mentoring ability to complement the Dynamic Dashboard
- ❖ Map different countries/government policies for antimicrobial R&D and accelerated approval pathways
- ❖ Establish a virtual funding consortium comprised of Global AMR R&D Hub Board members
- ❖ Publish reports on areas of underinvestment or where additional action is needed
- ❖ Identify R&D priorities for animal health
- ❖ Identify and establish mechanisms for stimulating public-private partnerships on animal health AMR-related health technologies, particularly for the development of new therapeutics, vaccines and alternatives to antibiotics
- ❖ Identify ways to incentivize R&D into alternatives to antibiotics for use in agriculture
- ❖ Review different mechanisms to incentivize behavioural change in farmers
- ❖ Hold a workshop that brings together PDPs working to address AMR so that lessons learnt and best practices can be shared and to improve collaboration among existing entities, implementation agencies and PDPs working in the AMR space
- ❖ Set global targets of what novel compounds and health technologies are required to meet the public health needs
- ❖ Evaluate existing subscription and pooled procurement mechanisms, to inform where governments can come together around a market mechanism to fix that part of the challenge
- ❖ Identify and evaluate different ways to obtain sufficient, diverse, predictable and sustainable funding for partnerships
- ❖ Propose ways on how to ensure that low-and middle-income countries are equal partners in any response to AMR
- ❖ Examine and review the different collaborative mechanisms used to fund AMR R&D
- ❖ Map the different groups/companies working in the AMR field to help small startups and SMEs to identify partners
- ❖ Expand and secure funding for early development stages (before human proof of concept)
- ❖ Expand and secure incentives and funding for diagnostics



Session 1 – Identifying research gaps to address AMR relevant to the Asia Pacific Region

Summary

Session 1 of the conference showcased recent AMR solutions being implemented in the Asia Pacific region such as accelerators and incubators (like CARB-X and CDDEP Surveillance), India's AMR Biorepository and RePORT platform for TB as well as Wellcome Trust's pilot Clinical Trial network. The Global AMR R&D Hub's Dynamic Dashboard was regarded as an important foundation for developing a global voice for AMR R&D and for establishing global R&D priorities that can then be adapted to local settings.

The discussions during the session emphasized the importance of a coordinated and cooperative approach across sectors and countries, breaking down data silos and overcoming barriers to collaboration. Using the advantages of data for evolving into a more active role; ideas to use it to 'seed' other partnerships and connections, as conduit for deeper engagement and therefore facilitating connection between actors (including research groups), for driving the agenda, it's important role in 'integration' and having value at an implementation level was also emphasised. Concretely, suggestions were made for both an overall global-level policy paper as well as thematic policy papers. It was also suggested for the Global AMR R&D Hub to become a 'meeting place for generating ideas' and facilitating networking and integration globally and within countries

Purpose

To hear how countries and organisations identify AMR research gaps, what these gaps are, and then discuss how to identify research gaps at a global level that are still applicable at country and regional level.

Format

Moderated session that included:

- A keynote presentation from the World Health Organization's Western Pacific Office
- A presentation from the Global AMR R&D Hub secretariat
- Presentations from representatives from the Pacific Islands, Vietnam, China, India and Wellcome Trust
- A panel discussion

Recommendations arising from the panel discussion

Establish strong global or regional thematic platforms/networks of research groups that have a common agenda and goal

Discussion points

- Identify convergence of efforts at global, regional and national levels, via the Dynamic Dashboard, and use this as the basis forming the thematic platforms/networks
- These platforms could also link research groups and accelerate R&D on specific compounds or products
- Networking through an integrated approach is needed, there are currently quite limited opportunities for exchanging information, especially for junior researchers, but this is important to find solutions at global and also at a local level.
- Even holding research/scientific meetings of thematic areas would be of great benefit, this would facilitate better engagement of researchers/research groups working on similar areas from different countries and reduce duplication.
- Would give more ownership by the key stakeholders.
- The Hub should be a conduit to connect various initiatives.

Develop policy white papers that outlines the global AMR R&D gaps and solutions and that present a global consensus (common voice)

Discussion points

- The Global AMR R&D Hub should be more than just the Dynamic Dashboard and it should play a larger role in the policy debate.
- The policy white paper should explore where we are today, what are the challenges we are going to face, where are the public health and R&D investments that need to come, how to build the human resources, how to create the pipeline of antibiotics, the surveillance needs and how to avoid the misuse of antibiotics.
- Having a global agreed voice will help to create a sense of urgency and awareness of what is required.

Develop a matchmaking database that lists researchers and research groups and their areas of expertise and mentoring ability to complement the Dynamic Dashboard

Discussion points

- Researchers can use to make their own connections at an individual level to help review research or applications to enable researchers to connect and make their own networks.
- To share the wealth of knowledge and experiences with early-stage researchers.

Map different countries/government policies for antimicrobial R&D and accelerated approval pathways

Discussion points

- Could be used to accelerate approvals through different countries
- Countries could learn from other country's policies – what has worked

Establish a virtual funding consortium comprised of Global AMR R&D Hub Board members

Discussion points

- Could Board members pledge part of their own national funding to become a virtual consortia and fund agreed priorities?
- Different models could be explored (e.g. bilateral, multilateral) but all working towards agreed priorities.
- This could bring in a collective responsibility and ownership of tackling AMR.

Publish reports on areas of underinvestment or where additional action is needed

Discussion points

- Areas identified include surveillance of antimicrobial usage across all sectors, implementation research (such as research investigating IPC and stewardship), integration/collaboration between human and animal health R&D
- Advocate for better/more integration between human and animal health R&D.

Presenters

<p>Socorro Escalante <i>Coordinator, Essential Medicines and Health Technologies Unit, Division of Health Systems, WHO Regional Office for the Western Pacific</i></p> 	<p>Framework for Accelerating Action to Fight Antimicrobial Resistance in the Western Pacific Region</p> <ul style="list-style-type: none"> ▪ Action of the WHO in the Western-Pacific region was presented. The framework is given by accelerating implementation of agenda and national action plans, catalysing opportunities from global and regional activities and strengthening existing regional mechanisms. The framework is intended to be future-oriented, create movement, be sustainable and grounded. ▪ Key priorities in the region for 2020/21 are to strengthening systems to combat AMR: surveillance systems, regional guidance and development; response to AMR outbreak: regional guidance development; monitoring antimicrobial consumption for the region; antimicrobial stewardship. ▪ The “stewards of the future” initiative calling for 1 million pledges to combat AMR and the Western Pacific Region Antimicrobial Consumption Surveillance System (WPRACSS) were presented.
<p>Elmar Nimmesgern <i>Secretariat Lead, Global AMR R&D Hub</i></p> 	<p>The Global AMR R&D Hub's Dynamic Dashboard</p> <ul style="list-style-type: none"> ▪ A first comprehensive report of the Dynamic Dashboard was published in November and recommendations by the Global AMR R&D Hub’s Board were submitted to the G20. ▪ Overall information available was contrasted with data for the Asia-Pacific region. One sees some differences such as a larger share of investment going towards operational and implementation research, in line with the priorities set by National AMR Action Plans in the region.
<p>Eka Buadromo <i>Senior Laboratory Advisor, The Pacific Community</i></p> 	<p>Challenges faced by AMR - strengthening activities in the Pacific Island Countries</p> <ul style="list-style-type: none"> ▪ The significant threat that antimicrobial resistance presents in the Pacific Island countries, LMICs with economic challenges and remote location, was presented. There are many challenges such as lack of regulations, poor access to antibiotic treatment combined with high infection rates, irrational prescribing and lack of resources, infrastructure and trained staff such as veterinarians. ▪ Support from the WHO for developing AMR action plans was acknowledged. The aim is to improve awareness and understanding, strengthen surveillance, reduce incidence of AMR, optimise use of medicines, sustainable investment, and governance to combat AMR. ▪ Concrete actions have been taken with the development of a standard training curriculum on microbiology AMR diagnostic methods, lab-based surveillance, IPC and antibiotic stewardship. Training rolled out to four countries so far and more to follow.

<p>Jiang Jian-Dong <i>President Institute of Pharmaceutical Sciences Chinese Academy of Medical Sciences</i></p> 	<p>Anti-AMR drug research in China</p> <ul style="list-style-type: none"> ▪ The broad-ranging efforts in China on AMR R&D were presented. Government invested about 100 m USD in the last five years addressing for example target identification and screening efforts, including prospecting for synergistically acting molecules from Chinese traditional medicine. ▪ Challenges in this effort (such as maturing hits to leads) and the importance of industrial involvement to progress compounds were mentioned. With ten major companies active in the antibiotic field, 45 drug candidates are being prepared for clinical studies, seven molecules are in clinical trials and two new medicines (based on existing scaffolds) were approved. ▪ Monitoring of drug-resistant isolates of AMR occurs through the nationwide China Antimicrobial Resistance Surveillance System – CARSS as well as systems around Beijing and Shanghai. Most AMR has declined but carbapenem-resistant Klebsiella has increased. ▪ Efforts have been taken to improve prescribing of antibiotics through training for doctors and pharmacists as well as students in these domains. ▪ International collaboration is encouraged, especially with the USA and Europe. There are also direct interactions between Chinese and international scientists.
<p>Juan Carrique-Mas <i>Senior Veterinary Researcher, Oxford University Clinical Research Unit, Vietnam</i></p> 	<p>Targeting veterinary drug shops in Vietnam. A way forward to reduce antimicrobial use and potential tool</p> <ul style="list-style-type: none"> ▪ A pilot to develop and implement a system for monitoring antimicrobial use in Vietnam was presented. Country has close to 100 million population and is still mostly rural. High antibiotic use of 3800 tons per year, 70% of which in farms, which are dominated by small farms (90%). ▪ Large number of veterinary drug shops (1 per 6 km²). Catalogue of the large number of licensed antimicrobials was created (info found for half of the about 7500 products). 92% contain at least two active ingredients and large majority represent antimicrobials defined as high or highest priority by the WHO. ▪ Application for data collection at retail was developed and tested, plan to cover most of the country through staggered data collection in different regions. This would allow to see which antibiotics are used and for which species. ▪ How to put the data into context was discussed, several methods available. Example of reductions in use following availability of antimicrobial use information in the EU was mentioned.

<p>Chibuzor Uchea <i>Research Advisor, Wellcome Trust</i></p> 	<p>International Clinical Trial Networks</p> <ul style="list-style-type: none"> ▪ The Wellcome Trust-led effort of creating a clinical trial network in South-East Asia was presented. Goal is to arrive at relevant, informative and actionable data. Current landscape with high cost for building capacity for a specific trial, only for this to be disbanded after the study was presented as highly inefficient. ▪ Intl. clinical trials networks in LMICs can also be platforms for innovative trial designs including continuous master protocols with shared use of control groups; the two aspects are independent but joint implementation would provide greater efficiencies. ▪ Benefits of such networks for sponsors, investigators and patients such as reduction of cost, time savings, greater pool of patients, quicker access to new interventions. Challenges are that robust governance is vital but difficult to achieve; data management issues; sites want to also do independent research, issue of underuse of networks between studies. ▪ The Wellcome Asia network to be launched early 2021, with a pilot study centre in Singapore; investigator-initiated studies to start, later expanding to industry studies with higher degree of centralization. 	
<p>Renu Swarup, <i>Secretary Department of Biotechnology Ministry of Science & Technology Government of India</i></p> 	<p>India's strategy for managing AMR R&D</p> <ul style="list-style-type: none"> ▪ From the view of India AMR was presented as a major global health issue. R&D challenges are complex, with unclear market potential and a weak pipeline of new antibiotics, the issue needs to be addressed globally. ▪ Indian National Action Plan led by government with broad involvement launched in 2017, following extensive consultation. Several lines of action include awareness and understanding, IPC, optimise use, innovations and R&D. The DBT "mission AMR" includes R&I on innovations and a major bio-repository of resistant strains from India established in Pune. ▪ The partnership with the Bill & Melinda Gates Foundation for Grand Challenges India was mentioned with focus on surveillance, IPC and R&D to remove antibiotics/antimicrobials from effluents. India is active in a number of international partnerships such as CARB-X. The success of international collaborations for developing Covid-19 vaccines was mentioned as an example to follow for AMR. ▪ As the way forward accelerate progress in countries, collaborate for more effective action, invest for a sustainable response and innovate to secure the future were mentioned. 	
	<p>Session moderated by Norman Swan, Medical journalist</p>	 <p>Session closed by Catherine Kelaher <i>Australian Government Department of Health and Global AMR R&D Hub Board Member</i></p>



Session 2 – Filling AMR R&D gaps in animal health at country, regional and global level

Summary

Session 2 of the conference highlighted the importance of addressing the AMR threat in a coherent, comprehensive and multisectoral global action encompassing all One Health sectors. Particularly, the promotion of international collaborations, including LMIC, and public-private partnerships were emphasized as key for the development of new therapeutics and preventives as well as alternatives to antibiotics. The need to incentivize R&D of alternatives to antibiotics for use in agriculture and putting well-defined regulatory processes in place were also raised. But also mapping of ongoing research was identified as critical to help set priorities and maximize the impact of resources invested in R&D.

Purpose

To hear how countries and organisations are trying to fill their identified animal health AMR research gaps and then discuss if any of these approaches can be coordinated and harnessed by others or incorporated into any regional/global response.

Format

Moderated session that included:

- A keynote presentation from the World Organisation for Animal Health (OIE)/STAR-IDAZ IRC Secretariat
- A presentation from the Global AMR R&D Hub secretariat
- Presentations from the United States, Israel, the CGIAR Hub on AMR and Health for Animals.
- A panel discussion

Recommendations arising from the panel discussion

Identify R&D priorities for animal health
<ul style="list-style-type: none">▪ The Global AMR R&D Hub's Dynamic Dashboard is a useful tool for mapping investments in different countries, regions and research areas.▪ Need to ensure the data in the Dynamic Dashboard is as comprehensive as possible.▪ Need to know what the R&D priorities are in animal health so that the information in the Dynamic Dashboard can be mapped against these. This would then enable identification of underfunded areas and coordination and formation of international collaborations around the identified priorities.▪ Collaborations will need to happen with a range of partners from private companies to local partners to ensure research is useful and relevant.▪ A paradigm shift is needed on how R&D of diagnostics, vaccines and therapeutics is approached.
Identify and establish mechanisms for stimulating public-private partnerships on animal health AMR-related health technologies, particularly for the development of new therapeutics, vaccines and alternatives to antibiotics
<ul style="list-style-type: none">▪ Public-private partnerships will help transfer discovery stage research to industry so that they can make the investment and bring a product to market.▪ More flexible regulatory processes for approval of novel products or innovative spaces is needed particularly for alternatives to antibiotics.▪ Alternatives to antibiotics play a role particularly in the preventive space and might help to lower the preventive use of antibiotics.▪ It will be important to ensure that alternatives to antibiotics will work in LMIC and are affordable.
Identify ways to incentivize R&D into alternatives to antibiotics for use in animal health
<ul style="list-style-type: none">▪ There is a lack of incentives for pharmaceutical companies to make the investment into alternative to antibiotics. There also needs to be a clear regulatory pathway.▪ Translational research for technology transfer.
Review different mechanisms to incentivize behavioural change in farmers
<ul style="list-style-type: none">▪ Learn and draw from experiences in different sectors.▪ Identify sustainable incentives that are also applicable to small holder livestock farmers (focus LMIC).▪ What works and when/where and what has not been successful.

Presenters

<p>Stefano Messori <i>World Organisation for Animal Health (OIE)/STAR-IDAZ IRC Secretariat</i></p> 	<p>Collaborating on prioritisation and coordination of AMR R&D for animal health</p> <ul style="list-style-type: none"> ▪ OIE was introduced as intergovernmental organisation established in 1924, with 182 member countries. Working on priority animal diseases and horizontal topics and animal health issues with public health implication such as AMR. ▪ OIE strategy on AMR and prudent use of antibiotics supports Global Action Plan on AMR and is structured around improving awareness and understanding, strengthening knowledge through surveillance and research, supporting good governance and capacity building and encouraging implementation of international standards. ▪ The strategy recognises that research plays an important role. Target of research is vaccines! Example of furunculosis vaccine in salmon farming leading to plummeting antibacterial use was shown. To identify priority diseases for animal vaccines OIE has published reports as regards pigs, poultry and fish as well as cattle, sheep and goats. Work took into account both bacterial infections and other infections driving antibiotic use. Overall recommendation to establish a global vaccine research network and to establish public-private partnerships. A second important target for R&D is alternatives to antibiotics, where OIE has supported USDA in workshops on this topic. Importance of regulatory pathways was raised. ▪ STAR-IDAZ International Research Consortium (IRC) introduced as global network of public and private funders of animal health research, identifying priorities, gaps and research roadmaps. Importance of horizon scanning mentioned, Global AMR R&D Hub can play a role here, this will help to advocate for uptake of the roadmaps. ▪ Overall, the importance of coordination and collaboration in AMR was highlighted, across sectors (animal/human). Also avoiding duplication and sharing of results is key in view of limited resources. Public-private partnership on health technologies need to be stimulated.
<p>Elmar Nimmesgern <i>Secretariat Lead, Global AMR R&D Hub</i></p> 	<p>The Global AMR R&D Hub's Dynamic Dashboard</p> <ul style="list-style-type: none"> ▪ A first comprehensive report of the Dynamic Dashboard was published in November and recommendations by the Global AMR R&D Hub's Board were submitted to the G20. ▪ Overall information available was summarized. The investments made into the animal and human One Health sectors were compared: relatively larger share of investment in the human sector going towards therapeutics development and a relatively larger share of investment in the animal sector going towards preventives. ▪ Product-related investment in the animal health sector represent over 40% of total investment and is targeted mostly at preventives (vaccines!) and diagnostics. Animal groups addressed are livestock, poultry and aquaculture (in this order). ▪ Examples of bilateral partnerships between countries that address animal health-related AMR R&D were shown.

<p>Arshnee Moodley CGIAR Hub on AMR</p> 	<p>Knowledge, attitudes and practices amongst small holder livestock farmers in Africa- showing unmet research needs</p> <ul style="list-style-type: none"> ▪ Focused on small holder livestock farmers as they provide nearly 50% of the world’s livestock and cereals and close to 70% of the livestock and cereals in emerging and developing economies. ▪ AMR challenges in livestock sector in LMICs include: no information of burden of AMR in animals, limited access to veterinary services, limited diagnostic capability, little to no surveillance (AMR or AMU), lack of cost-effective alternatives, substandard counterfeit antibiotics, and little knowledge amongst users and prescribers. In addition, donor investment has a limited life and areas may not align with reality on the ground ▪ AMR interventions in LMICs can include: regulations, surveillance programs, awareness and education campaigns, cost effective alternatives, improving herd health and access to veterinary services, and incentives to change behaviour. Possible to draw on lessons from food safety interventions.
<p>Cyril Gay Senior National Program Leader, Animal Production and Protection, Agricultural Research Service, United States Department of Agriculture</p> 	<p>The road towards the research and development of alternatives to antibiotics in the United States</p> <ul style="list-style-type: none"> ▪ There is a need for development of alternatives to antibiotics in agriculture antibiotics which is recognized in many national AMR documents. ▪ A paradigm shift is needed on how we approach the research and development of diagnostics, vaccines and therapeutics ▪ Defining mechanisms of action will be paramount to enable the effective use of alternatives to antibiotics in animal agriculture ▪ A portfolio of alternatives to antibiotics may need to be considered to achieve optimum health and disease management for different animal production systems ▪ There is a critical need to incentivize the research and development of alternatives to antibiotics for use in agriculture.
<p>Jeffrey Watts Research Director, External Innovation – Anti-Infectives, Zoetis</p> 	<p>Innovation in Novel Antibacterials in Animal Health</p> <ul style="list-style-type: none"> ▪ Animal health industry is highly regulated and is constrained by this environment. ▪ The need for novel antibacterials to treat animal diseases that are not shared with human medicine. These novel agents must fit the regulatory structures for specific treatment claims (prevention, control, treatment). ▪ Animal health companies continue to invest heavily into the R&D of novel anti-infectives including both preventatives and treatments. This includes novel small molecules that are not shared with human health and alternatives to antibiotics such as antimicrobial peptides, anti-virulence agents, immunomodulators, and microbiome modifiers. ▪ In order to ensure that novel solutions are available to producers, a well-defined regulatory process is critical for success
<p>Shlomo Blum Head of Bacteriology and Mycology Lab at Kimron Veterinary Institute, Israel</p>	<p>Animal AMR in Israel: research examples and gaps</p> <ul style="list-style-type: none"> ▪ Antimicrobial use in food animals is high in Israel and about 80% of antimicrobials are used in poultry.

	<ul style="list-style-type: none"> ▪ AMR research priorities include: epidemiological research on AMR prevalence in animals including developing systematic AMR monitoring system in food animals: quantifying the effects of antibiotic use (growth promoters) on AMR; understanding the sources of resistance; and developing alternatives to antimicrobials. ▪ Challenges and implementation gaps include that there is no national program for AMR in animals yet and no staffing resources allocated for AMR studies in animals. Collaboration and exchange of data between laboratories nationally can also be improved. 		
	<p>Session moderated by Nicola von Lutterotti <i>Science journalist</i></p>		<p>Session closed by Antoine Andremont <i>Scientific advisor, French Ministry of Higher Education, Research and Innovation and Global AMR R&D Hub Board Member</i></p>



Session 3 – Working together to fill AMR R&D gaps: collaborations and partnerships

Summary

Session 3 explored three different types of partnership models – product development, global multi-stakeholder and industry/private companies. The successes of the individual partnerships were showcased and the challenges, benefits and funding mechanisms for each one was discussed.

The importance of collaborations and partnerships was emphasized during the keynote presentation and that by working together in partnership, individual countries, organisations and/or companies can be greater than the sum of their parts. The Global AMR R&D Hub's Dynamic Dashboard captures a range of different partnership types formed to progress AMR R&D but highlights that only a small amount of funding is directed internationally.

Key themes that arose out of the panels is that obtaining sustainable and sufficient funding is challenging, that bringing together the different partnerships and funders to share their experience and expertise through workshops or publications would be beneficial, and that looking at partnerships outside the traditional AMR field may provide valuable insights.

Purpose

To discuss if, how and when different types of partnerships could be used to fill R&D gaps and where other types of partnership models may be more useful.

Format

Moderated session that included:

- A keynote presentation from the UK Special Envoy on AMR
- A presentation from the Global AMR R&D Hub secretariat
- Three concurrent panel sessions that included a chair and five panellists. The panels focused on product development partnerships, global multi-stakeholder partnerships and industry partnerships.

Recommendations arising from the panel discussions

Hold a workshop that brings together PDPs working to address AMR so that lessons learnt and best practices can be shared and to improve collaboration among existing entities, implementation agencies and PDPs working in the AMR space

- There is an urgent need for a concrete 2021 workshop to kick-off a 'AMR PDP-forum' to exchange learnings and best practices and improve collaboration among existing entities, implementation agencies and PDPs working in the AMR space; similarly, as is held for the PDP-Funders.
- The workshop should cover cross-cutting areas such as formulation/sub-population development, regulatory engagement, and global product roll-out.
- All current AMR-active PDPs are specialised according to pathogen or technology –this will pose challenges for AMR given the diversity and non-linearity of the challenge in these terms. By extension, AMR solutions are unlikely to lie in a single global 'AMR organization'. However, an initial narrow, singular, focus for a nascent PDP is not only extremely helpful but was even considered necessary for success.
- It was highlighted that the quicker expertise, capacity and experience is built-up the faster one can have impact (again the COVID example was highlighted). Yet as time goes on and PDP's mature, they collaterally develop non-obvious cross-cutting expertise and competencies that currently tend to languish within the silo in which they were built – this is where the value of collaboration was highlighted; to extract these learnings and competencies and apply them more broadly to capitalize on these synergies across the AMR-related PDPs.

Set global targets of what novel compounds and health technologies are required to meet the public health needs

- Targets could be set either by output (XY in the next 10 years) or by productivity (X output over Y period).
- Run a model to determine how this would translate into an 'ideal pipeline' to reach the goal. Review this against the current pipeline to understand the current scale of the 'gap'.
- By employing a 'portfolio approach' as in the industry, this would enable donors and PDP's to work backwards and a) for PDPs to state what their needs are to reach that b) for donors to review the PDP landscape and look at the sufficiency of its coverage and collective orientation – perhaps carving out 'space/mandate' for 3 (or so) x PDPs.

Evaluate existing subscription and pooled procurement mechanisms, to inform where governments can come together around a market mechanism to fix that part of the challenge

- Challenge of reconciling the debated public health priorities with the market incentives running in the opposite direction – the higher the public health needs the worse the investment case under the current market model. i.e. that identifying those patients which would be non-responders to current treatment would eliminate 90% of a developer's returns, worsening the investment situation further.
- The classic market model will not work for AMR, (in a different way than malaria and TB).
- Market incentives that pool demand, delink revenue from use, and provide a minimum market guarantee will be imperative.
- However, it is not just the model on which governments must agree but also the collaboration around the model – as it won't work if implemented country-by-country.

Identify and evaluate different ways to obtain sufficient, diverse, predictable and sustainable funding for partnerships

This should include

- Ways to attract new funders/donors into funding AMR R&D including how to involve BRICS countries and international aid funders, and
- Innovative funding mechanisms employed for established organizations (not just in the AMR field).

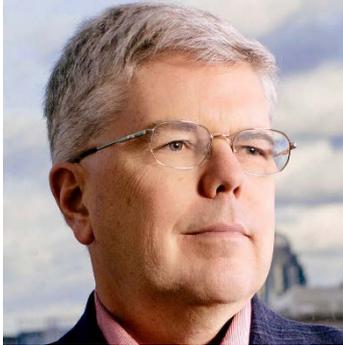
Supporting discussion points included

<ul style="list-style-type: none"> ▪ The impact of value proposition of research/product relevant to high burden countries – can the work of CEPI be used as a model for this? ▪ Informing and educating countries who are not traditionally involved in multilateral funding about how it works, how to implement in their country (overcoming legal issues) and the benefits such a mechanism can bring ▪ Unitaaid was highlighted as an example for innovative funding mechanisms such as the combination of the airline ticket levy, the CO2 tax and bilateral contributions.
<p>Propose ways on how to ensure low-and middle-income countries are equal partners in any response to AMR</p>
<ul style="list-style-type: none"> ▪ This does not have to be partners financially but may include in-kind contributions. ▪ Important to ensure the research and products are relevant and accessible to the people that need them the most. ▪ Look at organisations and partnerships that do this successfully.
<p>Examine and review the different collaborative mechanisms used to fund AMR R&D</p>
<p>The review should:</p> <ul style="list-style-type: none"> ▪ Include a range of different mechanisms used from how JPIAMR coordinates funding of different countries to the more traditional funding approach of a grant provided to a partnership like GARDP to disperse. ▪ Identify the advantages and disadvantages of each of these and if any of these mechanisms could be optimized and used further? ▪ Look at how to improve collaboration and engagement with funders after funding has been provided. Is there an opportunity here to use knowledge, experience and/or infrastructure of funders to enhance R&D work?
<p>Map the different groups/companies working in the AMR field to help small start-ups and SMEs to identify partners</p>
<ul style="list-style-type: none"> ▪ This mapping could start by improving the granularity or functionality of the Dynamic Dashboard. ▪ Could be a complementary database to the Dynamic Dashboard that identifies companies, expertise and current work area. ▪ Linkages with recommendations from session 1.
<p>Expand and secure funding for early development stages (before human proof of concept)</p>
<ul style="list-style-type: none"> ▪ Sweet spot for partnerships between small biotech and big pharma is around proof of concept in human (for Phase II studies). Because of challenging financial and funding situation, small biotech companies are forced to enter partnerships earlier in the process (lead optimization). ▪ If additional funding would be available in the earlier stages of development, then partnerships could be sought and formed slightly later in clinical development which would reduce IP dilution.
<p>Expand and secure incentives and funding for diagnostics</p>
<ul style="list-style-type: none"> ▪ Overcome the critical financial situation for diagnostic companies. This is especially important when working on tools for narrow spectrum drugs, niches, and small regional markets and would help to establish partnerships with small companies which will not develop AST (antibiotic susceptibility tests) themselves due to budget constraints.
<p>Promote and communicate best practice partnership models</p>
<ul style="list-style-type: none"> ▪ Results of R&D are published but the strengths and challenges of different partnership models are not. This type of information, if available would help to identify the best way forward for the beginning of partnerships and potentially streamline the approach. ▪ Look at partnership success stories from outside the traditional AMR to draw in lessons learnt and key points for success – for example ViiV Healthcare.

Presenters

<p>Dame Sally Davies <i>UK Special Envoy on AMR</i></p> 	<p>Keynote presentation</p> <ul style="list-style-type: none"> ▪ AMR is a global issue of such a scale, complexity and urgency that it necessitates a truly global response. COVID-19 demonstrates that this is possible and together countries can be more than the sum of their parts ▪ Global collaboration cuts across countries, organisations and sectors. it comes in many forms – we need to work together to share knowledge, best-practices and lessons learnt. But action is also needed at national, regional and individual levels to ensure sustainability and impact. ▪ For COVID-19 there is a knowledge gap but for AMR there is a doing gap. Data will drive political momentum and will also enable us to get to the heart of the problem. ▪ As we seek to build-back-better from COVID, and prepare for future pandemics including AMR, the slow pandemic happening now, the UK will be using its G7 presidency to improve the antimicrobial drug pipeline, ensuring the value-chain is safe, secure, sustainable and stewarded. The research commissioned by the Global AMR R&D Hub will be essential for this. ▪ Together working nationally, internationally, across borders and across sectors, we can collaborate to secure our sustainable future of antibiotics. We all need to play our part and think outside the box to ensure everyone, everywhere, can access the treatments they need.
<p>Elmar Nimmesgern <i>Secretariat Lead, Global AMR R&D Hub</i></p> 	<p>The Global AMR R&D Hub's Dynamic Dashboard</p> <ul style="list-style-type: none"> ▪ Many different partnership approaches for AMR R&D including international or coordinated funding to achieve agreed priorities, across One health sectors, product development partnerships and amongst private companies. ▪ The Dynamic Dashboard shows that only 10% of funding captured goes to a recipient outside of the funder's country (international funding). This increases to 28% if all European Union funding is considered international. ▪ Examples of animal health and/or One Health bilateral initiatives captured in the Dynamic Dashboard include: Innovative Veterinary Solutions for AMR / InnoVet-AMR (Canada and UK), China-UK Innovation Collaboration; Argentina and UK to address AMR in food production; Livestock Vaccine Innovation Fund (Canada and the Bill & Melinda Gates Foundation); and China and Germany (One Health). ▪ Examples of multilateral initiatives captured in the Dynamic Dashboard include JPIAMR, InfectERA, One Health EJP, and the Southeast Asia-Europe joint funding scheme.

Panel A - Product development partnerships



Chair - Kevin Outtersen



Cecilia Ferreyra, FIND



Erin Duffy, CARB-X



Jörg Möhrle, Medicines for Malaria Venture



Marit Metternich, German Federal Ministry of Education and Research



Willo Brock, TB Alliance

- Government intervention generally targets the early research space and product development where the private market does not function optimally for all, i.e. where there is large inequality of wealth such as with NTDs. Markets for AMR products are deeply flawed but in different ways than we are traditionally used to. Access starts with R&D and many participants highlighted that their PDPs work across the whole value chain from early development to implementation. Downstream partnerships and supply chain are necessary to deliver products to the market and to patients.
- Political leadership and funding remain the limitation more than the science in TB and AMR more broadly. One way or the other the public will be paying the bill (through push funding or prices) as such the public should set the priorities based on public health priorities. At the same time, governments should be held accountable for fulfilling both commitments made and the need for additional monies.
- These global health needs have high priority for the German government that has invested over €120 million in PDPs. In the last decade its view and portfolio for support has expanded into pandemic preparedness and AMR. PDPs are an important but only one part of the solution to ensure viable pipelines and both other approaches are needed.
- Leveraging COVID to demonstrate how working together faster and more efficiently is possible. Political willingness has a pivotal role in catalysing how implementation, new ways of working and innovation is feasible: the more you invest, the fuller the pipeline becomes, faster! COVID may or may not help with investment case but has shown an alternative route to the current slow, steady and certain approach typical of existing PDPs.
- Translation of an approved product to 'global health' (widespread use) was highlighted as one of the most difficult transitions to make. This is true for the current commercial model but also for the existing donor-supported implementation agencies (Medicine Patent Pool, Global Fund and GAVI) which were noted to have been game changing. Sharing the, often-hard, learnings from these organisations as well as from COVID and the PDPs will be critical. Aside from a single concrete example this collaboration and exchange of learnings was acknowledged as not yet happening.
- Operational research was highlighted as the current, most substantial gap in the area, within the existing actors/infrastructures (in part due to its cost).

- PDPs play a pivotal role ‘upstream’ on the topic of access and implementation particularly in embedding the thinking into developers from the outset (even as early as discovery). This happens formally through access/stewardship contract provisions but also more informally in the PDP’s mentoring of developers and ‘tuning’ their development programmes on topics like LIC-appropriate performance characteristics i.e. formulations. The limited experience of most current, very small, AMR developers in these respects was noted as was the greater leverage PDP’s/donors held during the R&D phases to embed these considerations because investments were still flowing.

Panel B - Global multi-stakeholder partnerships



Chair – Peter Beyer



Cornelis Boersma, Board Member
NADP/Professor Sustainable
Health and Innovation



Gabrielle Breugelmans , CEPI



Laura Marin, JPIAMR



Matthew Doherty, GARDP



Alexandra Cameron, Unitaid

- The different types of partners and funding/financing mechanisms were presented by the panellists
- The importance of complementary collaboration contributions in the complex AMR R&D landscape was emphasized and to avoid any competition. It needs to be a coalition of the doing.
- To be successful, any partnership formed should be in response to a clearly defined unmet need that has close and complementary relationships with other stakeholders in the field
- While each partnership had unique strengths, common ones identified included
 - Agility, speed, scope and access
 - Identifying and filling gaps as they move forward
 - Formation of strong partnerships
 - Opportunity to provide leadership in the field
 - Ownership of different partners in priorities identified and funded
 - Connecting partners/stakeholders to be able to take innovation and deliver this to the people who need it
- All partnerships identified obtaining sufficient, diverse, predictable and sustainable funding as the main challenge.

Panel C – Industry partnerships



Chair – Nicola von Lutterotti



Géraldine Saint-André, bioMérieux



Marc Gitzinger, BioVersys



Yves Crehore, RLDatix



Frederik Deroose, Asclepia



Sherene Min, ViiV Healthcare

- Different industry partnership models were presented and advantages and challenges were discussed.
- The advantages of industry partnership models raised were the access to additional and diverse expertise, ability to learn from each other, thought leadership and environment for innovative thinking, sharing of cost and risk, and being able to speed up or streamline R&D.
- The challenges outlined were that there is always a degree of risk or uncertainty, complexity of agreements and applications, depending on when the partnership happens then intellectual property can become challenging.
- A partnership between two big pharma companies in the field of combination therapy pulling together drugs from different companies or the development of companion diagnostics in a drug-diagnostic partnership highlighted some obvious beneficials of industrial partnerships.
- Communication is key – external, but even more so internal communication.
- In AMR, 80% of new antibiotics in clinical trials are produced by SMEs. Challenging financial situation of SME leads to earlier partnerships.



**Session moderated
by Nicola von
Lutterotti**
Science journalist



**Session closed by
Lynn Filpi**
*U.S. Department of
Health & Human
Services and Global
AMR R&D Hub
Board Member*