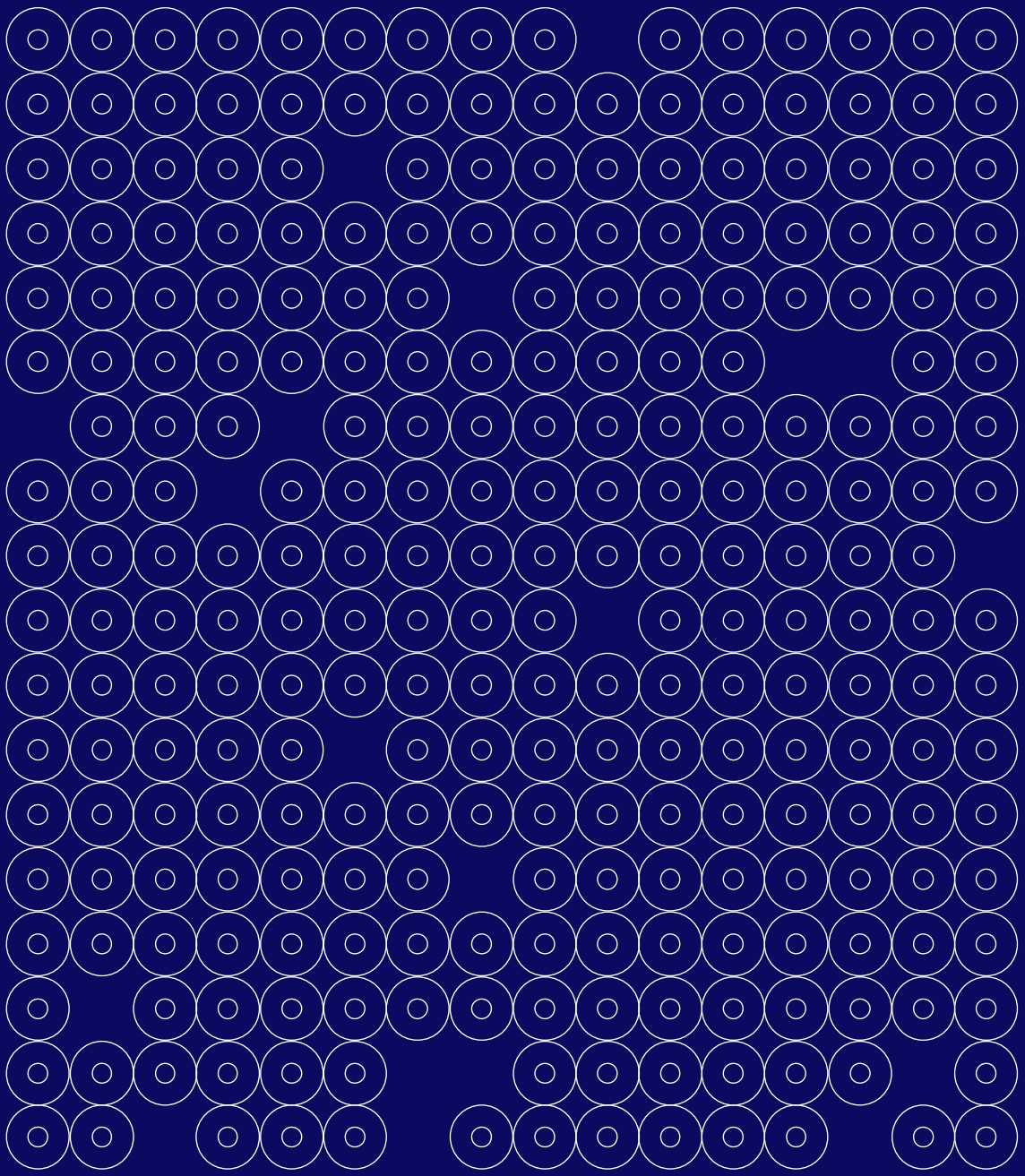
Developing Novel Antimicrobial Therapeutics

Online workshop 21 June 2022

CSA DESIGN OH AMR



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Executive Summary

In the research framework of Horizon Europe, the European Commission has identified 49 new European Partnerships, including the “One-Health AMR Partnership”.

To contribute to the European One Health Action Plan on AMR and WHO Global Action Plan against AMR, the Joint Programming Initiative on Antimicrobial Resistance (JPIAMR), together with other stakeholders, is leading the development of the One Health AMR partnership. To date, JPIAMR has invested over €125M and supported 99 projects and 38 networks.

One of the key priorities of the One Heath AMR partnership will be to improve the translation of its funded projects from academia to industry. Therefore, the aims of this innovation workshop “Developing Novel Antimicrobial Therapeutics” on therapeutics are as follows:

- Identify the gaps and challenges in the translation from academia to industry for diagnostic tools for drug-resistant infections in the human and animal space.
- Explore how the One Health AMR partnership can improve the translation of its funded projects.

The online workshop was organised on the 21 June 2022 by the Coordination and Support Action (CSA) DESIGN One Health AntiMicrobial Resistance (DESIGN OH AMR). The workshop was carried out by JPIAMR together with UKRI/Innovate UK KTN.

Fifty-four people registered to attend the meeting, representing nineteen countries mainly from Europe. The agenda and list of presenters can be found in Appendices 1 and 2. The workshop was divided in two themes:

- Challenges and opportunities to improve the translation of projects from academia to industry.
- Funding challenges for developing novel antimicrobial therapies.

The first theme included some scene-setting presentations followed by facilitated breakout discussions with all the attendees.

The second theme, funding challenges, included a presentation on the funding landscape followed by a panel discussion with global funders and input from the audience and national funders.

To improve the translation of funded projects from academia to industry, the following recommendations were made:

1. Establish a collaboration and coordination activity across the continuum of support (Global and national funders, incubators, accelerators, other stakeholders) to improve the support translation, implementation, and adoption of solutions.

2. Partnering with other stakeholders to provide academics, early entrepreneurs and staff working at knowledge transfer and commercialisation offices with translational knowledge. This could include workshops, boot camps, accelerators, etc.
3. Create an online platform as a repository of knowledge.
4. Explore with national funders continued funding for the funded projects.
5. Funded projects by the One-Health AMR Partnership should include a clear understanding of the market opportunity, competition, impact, and route to translation.
6. Provide good practice guides outlining examples of reasonable commercialisation deals between industry and academia.
7. Fund more focussed research and fail early.

Introduction

Background and objectives

A partnership on antimicrobial resistance

In 2021, the European Union (EU) launched "Horizon Europe", its framework funding programme for research and innovation. The creation of objective-driven and ambitious partnerships to support of EU policy objectives is one of the instruments deployed by the EU in this framework programme. In June 2017, the European Commission (EC) adopted the "EU One Health Action Plan against AMR" to address the emergency of antimicrobial resistance (AMR) and its consequences on public health. "Boosting research, development and innovation" is one of the three main objectives of this action plan and through the creation of a partnership "One-Health AMR (OH AMR)" the EC and Member States aim to support the research and innovation objectives of the EU Action plan against AMR.

Identification of Prioritised Research and Innovation Objectives for the candidate One Health AMR partnership Strategic Research and Innovation Agenda

The Coordination and Support Action (CSA) DESIGN One-Health Antimicrobial Resistance (DESIGN OH AMR) has been created in response to the HORIZON-HLTH-2021-DISEASE-04-05 call: "A roadmap towards the creation of the European partnership on One Health antimicrobial resistance (OH AMR)." The main objective of DESIGN OH-AMR is to prepare the launch of the OH AMR candidate partnership by identifying the Prioritised Research and Innovation Objectives (PRIOs) of the future partnership.
The candidate One-Health AMR Partnership is expected to connect and facilitate research and innovation in AMR field. Therefore, this workshop was designed to facilitate the exchange of ideas between various stakeholders to:

- Identify the gaps and challenges in the translation from academia to industry for diagnostic tools for drug-resistant infections in the human and animal space.
- Explore how the One-Health AMR Partnership could improve the translation of its funded projects.

The recommendations of this workshop will help the future members of the candidate One-Health AMR Partnership to take action to improve the translation of their funded projects for the benefit of humans, animals, the environment, and society at large.

Key figures

- This was a 3.5hr workshop and consisted of:
  - A set of scene setting presentations on challenges and learnings in the translation space
  - A presentation on the funding landscape
  - A panel discussion with global funders
  - A facilitated discussion in smaller groups on the challenges and potential solutions to improve the translation in therapeutics area.

- The number of participants was kept relatively low to be able to facilitate the discussion during the breakout sessions (see Agenda in Appendix 1).
- Fifty-four people registered to attend this workshop, including organisers, presenters, academic researchers, industry, national and global funders, and other enabling organisations.
- The geographical distribution of the registrants included nineteen countries, mainly from Europe with small participation from Africa America and Asia.
- The gender balance was 52% male, 48% female.
- Of the organisations present 22% were private sector organisations, 54% were public sector organisations (including academic research centres, government, and funding agencies), and 24% were not for profit organisations (including global funders and enabling organisations, some of them actively involved in research).

Europe		**Africa**		**America**		**Asia**	
Austria	2	Tanzania	1	Colombia	1	India	1
Denmark	2	Togo	1	USA	2		
Estonia	1	Uganda	1	Uruguay	1		
France	4						
Germany	7						
Lithuania	1						
Netherlands	1						
Norway	1						
Spain	5						
Sweden	3						
Switzerland	3						
UK	16						

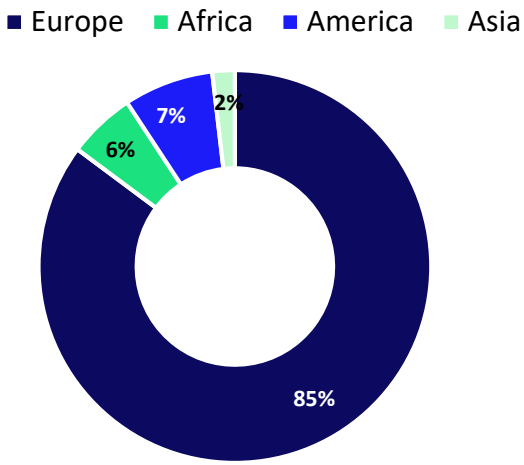

Figure 1. Geographical distribution of the participants (including organisers, presenters, academic researchers, industry, global and national funders, and enabling organisations).

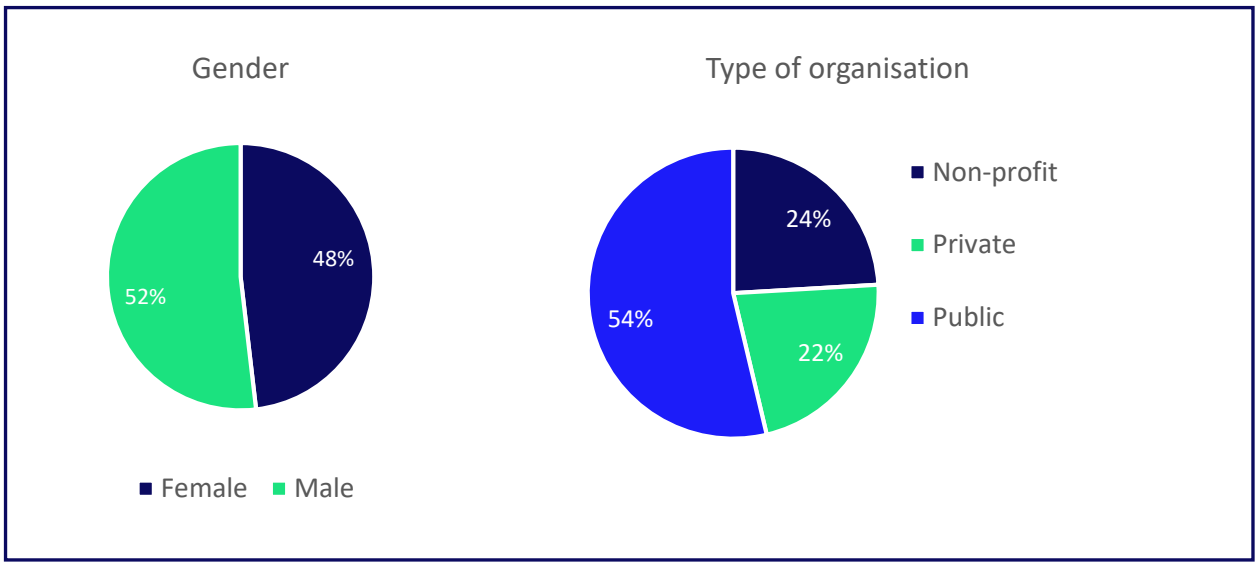

Figure 2. Public organisations include academic research centres, and government funding agencies. Not for profit include including global funders, and enabling organisations, some of them actively involved in research.

Workshop sessions

Session 1. Aims and challenges in developing new antimicrobial therapeutics

Presenter: Prof. Jordi Vila, Head of the Department of Clinical Microbiology, Full Professor of the School of Medicine of University of Barcelona and Research Professor of the Institute of Global Health of Barcelona. Member of JPIAMR Scientific Advisory Board.

Jordi, provided an overview of the challenges and impact of AMR in human health and its economic impact. He mentioned that the spread of AMR can be caused by drug-resistant bacteria and by drug-resistant genes which are important considerations when planning interventions to control the emergence and spread of AMR. He also emphasised the importance of having a One-Health approach, where the health of humans, animals and the environment are interconnected.

In 2017 the European Commission launched the European Action Plan against AMR, which had three objectives:

- Make the European Union a best practice region
- Boost research, development, and innovation
- Intensify the European Union efforts worldwide to shape the global agenda on AMR

In the research framework of Horizon Europe, the European Commission identified 49 new European Partnerships, including the "One-Health AMR Partnership", which is expected to be launched in 2025. Currently various stakeholders are working together to deliver the information needed to draft a new One-Health Partnership's SRIA that will built on the current JPIAMR's SRIA. The priority topics of the One-Health AMR partnership SRIA include:

- Therapeutics
- Diagnostics
- Surveillance
- Transmission and evolution
- Prevention and interventions

The topics will have a One-health approach but always considering the relationship and impact on human health. This partnership will also have cross-cutting themes such as: social sciences, innovation, implementation, and inclusion and diversity.

The new One-Health AMR partnership SRIA builds on the current JPIAMR SRIA[1]. The therapeutics working group of the candidate One-Health partnership is currently collecting information to update this new SRIA, which is expected to be ready for the launch of the One-Health AMR partnership in 2025.

[1] https://www.jpiamr.eu/about/sria/

Session 2. Industry's perspective – Improving transfer from academia in AMR drug development.

Presenter: Dr. Frederic Peyrane, Coordinator of the BEAM Alliance.

Biotech Companies from Europe innovating in Anti-Microbial resistance (BEAM Alliance) represents over 60 SMEs involved in developing innovative products to tackle AMR. The BEAM Alliance works with various stakeholders to implement strategies, polices and incentives for AMR innovation Europe.

Frederic mentioned that SMEs hold 80% of the AMR product portfolio worldwide in the pre-clinical and clinical stages, this is because most of large pharma have abandoned the field. However academic research laboratories are still active and collaboration between academia and SMEs is very helpful as it provides access to cutting edge science, infrastructure and it provides interaction to a network of practising scientific leaders.

He mentioned some of considerations for translation including:

- Low flow of projects due to lack of market attractiveness in the AMR field. Even a successful drug candidate generates low revenues after market approvals, making any investment an unattractive proposition.
- SMEs are concentrating their limited resources on their most advanced assets, which means that early stage in house programmes are not always a priority.
- Having a solid Intellectual Property (IP) portfolio usually in the form of patents is necessary to attract private investment. Although, having a patent is not always enough, challenges related to IP include:
- Having a long list of co-owners, especially universities, which can make the IP negotiations of commercial partnerships long, complex, and expensive.
- Weak IP, academic teams might not have the time, the resources, or the expertise to develop a strong IP portfolio. Weak IP is often difficult to defend.
- In some cases, to circumvent IP related pitfalls one need to be prepared to drop the original IP in favour of an industry co-owned stronger IP position. Publications should only be considered when strictly relevant and having prior working experience with industry is an advantage.
- The regulatory pathway should be well thought and feasible.

Session 3. Update on EMA actives to support AMR innovation.

Presenter: Dr. Radu Botgros, European Medicines Agency (EMA).

AMR is high in agenda for the European Medicines Regulatory Network which encompasses all the national competent authorities of the member states, and it is included in the European Medicines Network Strategy to 2025.

The Network has setup various ambitions to support AMR including fostering dialogue with developers of new antibacterial agents and alternatives to traditional antibacterial agents to streamline their development and provide adequate guidance in both human and veterinary medicine.

In the human health space, the main EMA activities to combat AMR are:

- Early engagement with developers of medicines that tackle AMR
- Creation of updated guidance for developers
- Interaction with international regulators
- Focus on alternative therapies (including bacteriophages, vaccines, monoclonal antibodies, anti-virulence approaches, antimicrobial peptides, oligonucleotides, nanoparticles, etc.) However, robust clinical evidence to demonstrate efficacy is required.
- Role in prudent use of approved antibiotics
- Make best use of regulatory tools to speed up approval for medicines addressing an unmet medical need
- Early engagement with developers of medicines that tackle AMR

The EMA's website contains guides that are useful for developers. Radu highlighted the following guides:

- EMA/CHMP/187859/2017 Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections to address paediatric-specific clinical data requirements.
- EMA/CPMP/EWP/559/95 Rev 3 / 2019 Guideline on the evaluation of medicinal
- products indicated for treatment of bacterial infections

Radu highlighted EMA's regulatory tools for medicines addressing unmet needs and the role of EMA's Innovation Taskforce to support innovative drug development. This is an opportunity for early dialogue for developers to brainstorm (free of charge) with the regulator for specific areas where no specific guidance exists[2].

The EMA also has a dedicated SME office, which is a good first point of contact for academics and SMEs to obtain regulatory advice[3].

Session 4. Innovative partnerships to foster global access to novel antibiotics

Presenter: Dr. Jean-Pierre Paccaud, Global Antibiotic Research and Development Partnership (GardP)

GardP was created by the World Health Organization (WHO) and Drugs for Neglected Diseases initiative (DNDi) in 2016 to ensure everyone receives effective and affordable antibiotic treatment, no matter where they live. GardP focuses on a public health-oriented portfolio through global public-private partnerships addressing WHO priority pathogen list. Their support includes co-development of clinical and pharmaceutical projects with partners to minimise costs and risks; leverage public and private funding, develop sustainable access strategies and promote sustainable reimbursement models.

[2] https://www.ema.europa.eu/en/human-regulatory/research-development/innovation-medicines#applying-for-a-briefing-meeting-section
[3] https://www.ema.europa.eu/en/human-regulatory/overview/support-smes

GardP is not a funding organisation, it is a developer that uses public funds to partner with SMEs and pharmaceutical companies to accelerate the development and improve global access to antibiotics via licensing agreements to make the products available for geographical markets that are of lesser economic interests to the companies.

Jean-Pierre highlighted the recent innovative access partnership deal on cefiderocol to treat antibacterial infections. Here Shinogi, the Clinton Health Access Initiative (CHAI) and GardP partner to expand the access for this product to 135 countries.

Session 5. Funding landscape

Presenter: Dr. Ralph Sudbrak, Interim Secretariat Lead at the Global AMR R&D Hub (Germany).

Ralph introduced the Global AMR R&D Hub, which was established in May 2018 following a call from G20 leaders for a new international collaboration to improve and enhance AMR research and development activities and policies across the one health spectrum. The hub is a partnership consisting of representatives of 17 countries, the European Commission, the Bill & Melinda Gates Foundation and the Welcome Trust.

One of Hub's main activities has been the development of the Dynamic Dashboard, which is a global knowledge platform for AMR R&D. It consists of three sections:

- Investment in R&D gallery
- Anti-bacterials in clinical development
- Incentives for anti-bacterials

It is worth noting that the information presented in the Dynamic Dashboard is from projects that were active in 2017 or later and comes only from public and philanthropic sources.

Each year the Global AMR R&D Hub produces a report outlining current funding information and highlights gaps and opportunities.

The dashboard shows that the overall investment in AMR since 2017 was $9.19 billion from public and philanthropic sources; this is approximately $1.8 billion annually. 42% was directed towards public-funded R&D projects focusing on therapeutics. Therapeutics attracts up to three times more public funding than diagnostics and vaccines. The private sector invests a similar amount annually ($1.8 billion). Ralph also highlighted the new AMR Action Fund that plans to invest approximately $1 billion to bring 2-4 new antibiotics to the market by 2030.

In the therapeutics space, funding for academic projects (40%) and for SME projects (37%) is similar. The main funders include the National Institute for Health (USA), the Innovative Medicines Initiate (EU), CARB-X (Global Partnership), and the Biomedical Advanced Research and Development Authority (USA).

A significant part of the funding is invested into WHO's priority pathogens list, especially in the high priority group. This is mainly because the Mycobacterium genus attracts a great deal of funding. There are however some bacterial genera in the priority list that don't receive or receive hardly any funding.

High-income countries (HICs) fund most of the research on therapeutics, but most of the funding also goes to organisations in HICs. There are some funders in HICs such as International Development Research Centre (IDRC) in Canada, the Swedish International Development Cooperation Agency (SIDA), the UK Department of Health and Social Care through their Fleming Fund, the Global AMR Innovation Fund (GAMRIF) and the International Centre for Antimicrobial Solutions (ICARS) in Denmark that fund research organisations in LMICs. However, the amount of funding for organisations based in LMICs is significantly lower than for organisations based in HICs. There are numerous funders in LMICs that fund research in their own countries, but the amount of funding is very low compared to the number of projects funded. This data is mainly from China and Brazil.

Looking at the funders in the AMR space, it is possible to see a funding gap in the translational path from hit validation to lead generation, which is the transition phase from academia into industry.

In August 2021, the Global AMR R&D Hub published the "Estimating global patient needs and market potential for priority health technologies addressing antimicrobial resistance" report[4]. This report was commissioned by the G7 finance ministers and was prepared in collaboration with WHO to provide an update on the development activities in the AMR space.

Ralph suggested the following recommendations for JPIAMR and the One-Health AMR Partnership to improve the translation of their funded projects.

- Establish support structures for academics and early-stage companies to understand the drug R&D process.
- Specific funding for joint academic and industry initiatives for education in translational and regulatory sciences
- Design Smart funding instruments. This might require coordination between different funders. This could include similar initiatives to the SME instrument, Open-source research, specific targeted research projects (STREP), pre-competitive collaborations like IMI COMBINE and IMI TRASLOCATION among others.

Session 6. Round table discussion - funders' perspective.

Chair. Dr. Ghada Zoubiane, International Centre for Antimicrobial Solutions (ICARS) (Denmark).

Panellists:
- Dr. Erin Duffy, CARB-X (USA).
- Dr. Helmut Kessmann, Incate (Germany).

[4] https://globalamrhub.org/wp-content/uploads/2021/08/EAG-Report_FINAL_20082021.pdf

- Dr. Timothy Jinx, Wellcome Trust (UK).

This session also included the participation of the audience, including national funders. Each of the panellists introduced their organisations and their funding focus and strategy.

Combating Antibiotic Resistance Bacteria Biopharmaceutical Accelerator (CARB-X)

CARB-X is a global non-profit implementation partner developing antibiotics, vaccines, and diagnostics to fight drug-resistant bacteria. It is funded by Biomedical Advanced Research and Development Authority (BARDA, USA), Administration for Strategic Preparedness and Response (ASPR, USA), UK Aid, National Institute of Health (NIH, USA), Wellcome Trust, Bill and Melinda Gates Foundation and the German Government.

CARB-X supports developers via competitive funding calls to address unmet medical needs focusing on the drug-resistant bacteria identified in WHO and CDC priority pathogen list. It provides non-dilutive funding, scientific, regulatory, and business support through its Global Accelerator Network. In the therapeutic area, they cover the funding gap from lead generation, lead optimisation, preclinical development, and demonstration of safety in clinical trials.

CARB-X current approach to funding “align by design” ensures that its therapeutics project portfolio is supported by the corresponding diagnostic tool during clinical trials and market uptake.

Incubator for antibacterial Therapies in Europe (INCATE)

INCATE is a not-for-profit organisation that brings together academic researchers, entrepreneurs, industry, and investors from across Europe to support the translational phase between academia and industry. INCATE provides advice, community building and non-dilutive funding (up to €250,000) to accelerate the development of treatments, diagnostics, and interventions and build a pipeline of investable companies to tackle AMR.

Wellcome Trust

Wellcome Trust is a politically independent charitable trust and a global funder focusing on improving various aspects of human health.

Currently, the antibiotics therapeutics pipeline is insufficient to meet the world's needs for treatments particularly for bacterial infections. There is an underinvestment in the space due to the market failure that exists for AMR related products. Wellcome’s strategy in the AMR space is to invest in key areas across the R&D ecosystem. It has invested in the first and second round of funding of CARB-X, and in the AMR Action Fund. Another critical element, is investing in people, training the next generation of experts.

Timothy highlighted some of the scientific challenges including the need to identify new of chemical scaffolds and targets, as well as improve the utilisation of drugs to prevent the emergence of resistance – Optimisation of pharmacokinetic and pharmacodynamic studies

need to be done much earlier in the R&D cycle. Also, it is necessary to support alternatives to antimicrobials and preventative approaches such as vaccines.

Highlights of the panel discussion session

The following funding gaps in the translation process were identified:

- Gap 1 - Early translation from academia to industry (hit validation and lead generation).
- Gap 2 - From registration as a therapeutic agent into a drug all the way to when the drug is being used.
- Gap 3 – There is not sufficient funding to address some of the research questions related to the uptake and use of drugs when they become available (need investment in social sciences).

More funding and funders are needed to work in the transition areas, where gaps tend to exist between funders.

Academics need more access to knowledge and networks. Making contacts with people that can help answer questions outside their expertise.

Collaboration and coordination across the continuum of support (funders, incubators, accelerators, other stakeholders) is vital to support translation, implementation, and adoption of solutions.

The UK is exploring supporting incubators in specific thematic areas in addition to their standard funding programmes.

INCATE could work with JPIAMR and the One-Health AMR Partnership by focusing on:

- Community building (co-organisation and marketing workshops, webinars, events)
- Creation of a knowledge database
- Provide more non-dilutive funding for young companies

There needs to be a strategy for funding analysing the impact that a given project could have beyond creating scientific knowledge (wider impact). The likelihood of the project progressing to clinical trials and ultimately have an impact on people and patients.

The sharing of what was didn’t work is as important as the reporting of what did work.

Germany focuses on global health supporting large push initiatives such as CARB-X, the Global AMR Action Fund and INCATE among others.

France has supporting funding structures to cover the entire technology readiness level space. Although within the French system, there are still some challenges to fund clinical trials as they don’t fall within the innovation space.

Breakout session – Facilitated discussion on translation challenges

For this session, the participants were divided in three smaller groups, two groups discussed the human health aspects and one group the animal health aspect.
The key questions discussed in all three groups were:

- What are the main barriers to translation from academia to industry?
- Are regulation systems worldwide geared up for the future need for antimicrobials?
- What do we need to solve this?
- How can the Candidate One Health AMR partnership help in these actions?

1. Academic capacity

- There is a need to improve knowledge of the entire translation process (from concept to market adoption). This would be especially useful for academics, early-stage entrepreneurs, and staff in the technology transfer and commercialisation office at universities.
- There is a conflict between academic and industry roles and expectations– division of time and labour between roles.
- Academics don't know who to talk to if they are interested in translating their research.
- Academics and universities want to keep hold of IP.
- Equity issues.
- Contracts to establish a collaboration with universities can be very complicated.
- There is no funding for early translation. Funding is available for getting from the 'how it works' stage to the 'is it safe' stage translational work is not of interest of academic research funders.
- Lead optimisation through to pre-clinical development are quite far apart. Specific expertise doesn't often exist in academia.
- There is no real difference between the need for more research into novel candidates, repurposing existing drugs, the ecology of transmission and precision medicine approaches.

Solutions:

- Partner with accelerators to equip academics with translational knowledge.
- Consider organising courses for technology transfer and commercialisation officers to understand the entire industry R&D system, financial investment and time to market required.
- Consider bootcamps on how industry works. Consideration needs to be given on the best way to implement this. Globally by global accelerators, JPIAMR and others or at a national and regional level.
- Provide guides for reasonable commercialisation deals between industry and academia.
- Employ staff with direct experience of sector at the universities' technology transfer and commercialisation offices.
- Fund more focussed research and, if you are going to fail, then fail early.
- Create an online repository of knowledge that can be accessed by everyone, everywhere. This could include a check list of requirements needed before exploring licensing or other commercial deals with industry.

- Incubators and accelerators (physical or virtual) could help with mentorship/ handhold academics and early-stage entrepreneurs to guide them through various aspects of the R&D process (INCATE as a model).

2. Commercial pull for translation

- There is a general need for more entrepreneurial environments (across AMR community and in academia in particular), to drive earlier stage work.
- AMR is not generally high on the priority list for corporate open innovation programmes
- There is a need for more translational projects with commercial relevance to drive earlier engagement by businesses
- The pipeline is too small
- Outpatient indications, including delivery at pharmacies is also important, but companies need to focus on hospital-acquired infections to secure/justify investment.
- Germany has useful programmes to combine public and private sector research; but there's not enough funding overall. In Germany, easier to allocate push funding than industry pull mechanisms
- More non-dilutive funding is needed for early-stage companies, to address 2-5m equity funding gap and allow companies to reach value inflexion point.
- Pharma and Biotech SMEs are very different.
- Projects need to generate the right data that will be attractive to industry and to funders.
- Projects need to meet a medical need and be clinically developed to the right level.

Solutions:

- Importance of corporate partnerships, in addition to public initiatives e.g., Blue Knight from J&J and BARDA are very effective.
- Public funders should recognise different risk profile for companies in this space, and that it's a relatively small community of companies (maybe only 10-15 awards needed per country per year, at perhaps c£1m funding level).
- Smart funding instruments to drive the pipeline – multi-sector and large consortia may not always be appropriate (IP) – SME Instrument, IMI, etc. (needs to include external paid drug discovery expertise).
- In context of G7 / G20, more wealthy countries could contribute to AMR translational funding to compensate for LMICs
- Reflect on the UK (England) model – "NICE Netflix model" – paid for the non-use of their product
- More public Sector money along the lines of e.g., GARDP, CARBX, AMR Action fund, other international initiatives

Recommendations

This section includes actions that JPIAMR could consider to improve the translation of their funded projects from academic research to industry.

1. Establish a collaboration and coordination activity across the continuum of support (Global and national funders, incubators, accelerators, other stakeholders) to improve the support translation, implementation, and adoption of solutions.
2. Partnering with other stakeholders to provide academics, early entrepreneurs and staff working at knowledge transfer and commercialisation offices with translational knowledge. This could include workshops, boot camps, accelerators, etc.
3. Create an on-line platform as a repository of knowledge
4. Explore with national funders continued funding for the funded projects.
5. Funded projects should include a clear understanding of the market opportunity, competition, impact, and route to translation.
6. Provide good practice guides outlining examples of reasonable

Appendix I. Agenda

JPIAMR Innovation Workshop: Developing Novel Antimicrobial Therapeutics

Date: 21st June 2022
Time: 13.00 - 16.00 CEST / 12.00 - 15.00 BST
Platform: Zoom meeting

Time (CEST)		
13.00	Welcome and aims of the meeting	Gabriela Juarez Martinez, Innovate UK KTN Laura Marin, JPIAMR.
13.10	Aims and challenges in developing new antimicrobial therapeutics	Jordi Vila, University of Barcelona
13.25	Industry's perspective – Learnings from collaborations with research institutions	Frederic Peyrane, BEAM Alliance
13.40	Regulatory considerations	Radu Botgros, EMA
13.55	Innovative partnership to foster global access to novel antibiotics	Jean-Pierre Paccaud, GardP
14.25	Breakout session 1: Gaps, barriers, and opportunities in the translation of novel antimicrobial therapeutics	All
14.50	Summary of the discussion	All
14.55	Break	All
15.00	Funding landscape	Ralph Sudbrak, Global AMR R&D Hub
15.15	Roundtable Discussion – Funders' perspective	Chair: Ghada Zoubiane, ICARS Tim Jinks, Wellcome Trust Erin Duffy, CARBX Helmut Kessmann, INCATE
15.25	Closing remarks and next steps	Gabriela Juarez Martinez, Innovate UK KTN

Appendix II. Biographies

Presenters

Erin Duffy (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator CARB-X). Erin is the Chief of Research and Development at CARB-X and has over seventeen years of drug discovery experience. Prior to CARB-X, she worked at Rib-X Pharmaceuticals (now Melinta Therapeutics) where she built a research team that translated the company's scientific platform into next-generation antibiotics that targeted the ribosome. Prior to Rib-X, Erin was the Associate Director of Innovative Discovery Technologies at Achillion Pharmaceuticals, where she was responsible for building the structure and computational teams and platform for their nascent antiviral efforts. She began her industrial career at Pfizer Central Research working in the computational and structural drug design team.

Frederic Peyrane (Biotech companies from Europe innovating in Anti-Microbial resistance research, BEAM Alliance). Frederic is the coordinator for the BEAM Alliance. He holds a PhD in medicinal chemistry and has over 15 years' experience working as innovation consultant and technology transfer officer.

Ghada Zoubiane (International Centre for Antimicrobial Solutions, ICARS). Ghada is the Head of Partnership and Stakeholder Engagement at ICARS. In her role, she is shaping and delivering on ICARS' mission, bridging the gap between evidence and practice, and working in close partnership with low- and middle-income countries. She was previously the Science and Innovation Lead on AMR at Wellcome, the AMR programme manager at the UK Medical Research Council developing and leading different areas of research including antimicrobial resistance, infectious diseases, and public health. During that time, she was on JPIAMR management board.

Helmut Kessmann (Incubator for antibacterial Therapies in Europe INCATE). Helmut has a Ph.D. in biochemistry and, since 1997, co-founder of several Biotech companies, most recently of T3 Pharma which develops bacteria for cancer treatment. His focus has been on Business and Corporate Development, closing and managing R&D alliances with Pharma companies, and secure financing through venture capital, non-dilutive funds, and public offerings. He is a member of Incate Management Team.

Jean-Pierre Paccaud (Global Antibiotic Research and Development Partnership GardP). Since 2017 Jean-Pierre heads the business development and corporate strategy activities of GARDP and contributed to its inception. Previously, since 2007 he was heading the business development and legal teams of the Drugs for Neglected Diseases initiative (DNDi), contributing to establish R&D partnerships with several global pharmaceutical companies as well as biotechnology companies and academic groups. He trained as a molecular and cellular biologist, and spent more than 18 years in academia, working in immunology, diabetes, and cell biology, and was tenured at the University of Geneva School of Medicine prior to create his own start-up and after which he joined DNDi.

Jordi Vila (University of Barcelona) Jordi is the Head of the Department of Clinical Microbiology, Full Professor of the School of Medicine of University of Barcelona and

Research Professor of the Institute of Global Health of Barcelona where he leads the. Antimicrobial Resistance Initiative. His research interest focuses on developing new drugs against multi-resistant bacteria and molecular tools for rapid diagnoses of infectious diseases. He is currently the president of the Spanish Society of Infectious Diseases and Clinical Microbiology. He is also member of the Scientific Advisory Committee of JPIAMR and is leading the therapeutics working group of the candidate One-Health Partnership.

Radu Botgros (European Medicines Agency, EMA). Radu is Senior Scientific Officer, focusing on Health Threats and Vaccines at the European Medicines Agency. He is an Infectious diseases specialist, and holds a medical degree (MD) from Carol Davila University of Medicine and Pharmacy, Romania.

Ralph Sudbrak (Global AMR R&D Hub). Since March 2022 Ralph has been the Interim Secretariat Lead at the Global AMR R&D Hub. Before this position, he was a Senior Scientific Officer at the same organisation. Previous to joining the Global R&D Hub, Ralph has been a consultant freelancer, guest scientist at the Max Plank Institute for Molecular Genetics, and project manager at Alacris Theranostics in Germany.

Timothy Jinks (Wellcome Trust). Timothy is Head of Interventions for the Infectious Disease team, where he leads Wellcome's work in advancing research and development for therapeutics and diagnostics, alongside research to support solutions for antimicrobial resistance. Previsoulsy, he led Wellcome's strategic priority area for combatting drug-resistant infections, deploying a budget of over £250 million. He was also responsible for a portfolio of Wellcome projects to support early-stage product development, which covered therapeutics, diagnostic and devices across several therapeutic areas, particularly infectious diseases and oncology. Timothy has over 10 years industry experience in biologic therapeutics R&D and commercial research services. He holds a BSc Chemistry from the University of Georgia, and masters and PhD from Princeton University.

Organisers

Francesca Hodges (Innovate UK KTN). Francesca is part of the Innovate UK KTN's Emerging Technologies and Industries team and works as a Knowledge Transfer Manager in emerging life science applications and horizon scanning. She is a microbiologist and has a background in biomedicine and antimicrobial resistance, specifically in the development of novel bacteriophage-based treatments for use as antimicrobials across health and agri-food sectors. During her PhD, Francesca worked at the interface of academia and industry through collaborations with multiple companies. As a result, Fran has extensive experience in translating basic science research into innovative, real-world solutions.

Gabriela Juarez Martinez (Innovate UK KTN). She leads on AMR, Vaccines, and the Microbiome within the Health team. She is a former Enterprise Fellow of the Royal Society of Edinburgh and founder and CEO of Centeo Biosciences, a scientific instrumentation company aiming to improve the protein crystallisation process by creating a product line of temperature-controlled microplates. The company raised £1.6m and achieved sales in 24 countries. After exiting Centeo, Gabriela became a senior consultant at BioNano Consulting,

working with academic groups at Imperial College and UCL to deliver industry-led projects. She has been a mentor at the Innovation Forum and EIT-Health chapter UK and Ireland. She holds PhD. in Bioelectronics (BioMEMs) from the University of Glasgow and a BS and MS in Biomedical Research from the National University of Mexico (UNAM).

Laura Marin (Swedish Research Council). Laura is the Head of Secretariat of JPIAMR which is hosted by the Swedish Research Council. Previously, she was responsible for Science Policy and Member Relations at the European Science Foundation. Back in 2008, she was team leader of the European Science Open Forum in Barcelona (ESOF2008) and Director of Operations at the Catalan Foundation for Research and Innovation. She holds an MSc by the Universitat Autonoma de Barcelona and an M.Litt. in Management, Economic and International Relations by the University of St Andrews.

Laura Plant (Swedish Research Council). She has a PhD in Microbiology from the University of New South Wales in Australia. She has a research background in the field of bacterial pathogenesis and immunity from the Nestlé Research Centre, University of Melbourne, and Karolinska Institute. Since 2013, Laura has worked in research administration with specialisation in research funding as a Grants Specialist at Karolinska Institute and as a Senior Research Officer at the secretariat of the Joint Programming Initiative on Antimicrobial Resistance at the Swedish Research Council.

Laura is engaged in management of projects funded by the European Commission, is a national Programme Committee Expert for Widening and ERA in the Horizon Europe framework programme and is the Swedish delegate in the Global AMR R&D Hub.

Matt Chapman (Innovate UK KTN). He leads on Medical Technology within the Health team, working closely with colleagues in the adjacent and increasingly converging fields of digital health and medicines, as well as with colleagues from other KTN teams (particularly manufacturing, materials and investment). He also leads KTN's place-based activity in the North West of England, convening colleagues from across the Innovate UK family of organisations to work together more effectively and to share best practice.

Matt's background is in R&D management and in manufacturing, originally in the aerospace sector and subsequently in healthcare. He studied Engineering and Design, Manufacture & Management at the University of Cambridge.

Sophie Gay (French National Research Agency-ANR). She is a scientific officer for transnational collaborations in the Biology & Health department. After a PhD in molecular oncology (Sorbonne Université, Paris), she moved to Milan (Italy) to pursue her research activity at the IFOM Cancer Research Center. She joined ANR in 2018 to manage national and multilateral programs. She is presently involved in the JPI HDHL, in the ERA-NET ICRAD, in the JPIAMR. In addition, in the framework of the CSA DESIGN, she is in charge of coordinating the drafting of the Strategic Research and Innovation Agenda (SRIA) of the candidate One-Health AMR Partnership.

Terry O' Neill (Innovate UK KTN). Terry is Head of Health. Previous roles include Industry Sector Manager at TWI Ltd with responsibility for the medical sector. Before TWI Terry

worked as a business development manager at the Norwich based technology transfer and intellectual property development company PBL. He has a background in project management in the biotechnology industry. Terry was a member of the Management Team at the physics start-up company Antenova where he managed the process of raising over £6m worth of private equity during the companies' series B funding round. Terry has also worked in the NHS.

Within the KTN Terry is the Head of Health responsible for managing the Health Team with priority activities in medicines development and manufacture, medical technologies and digital health.