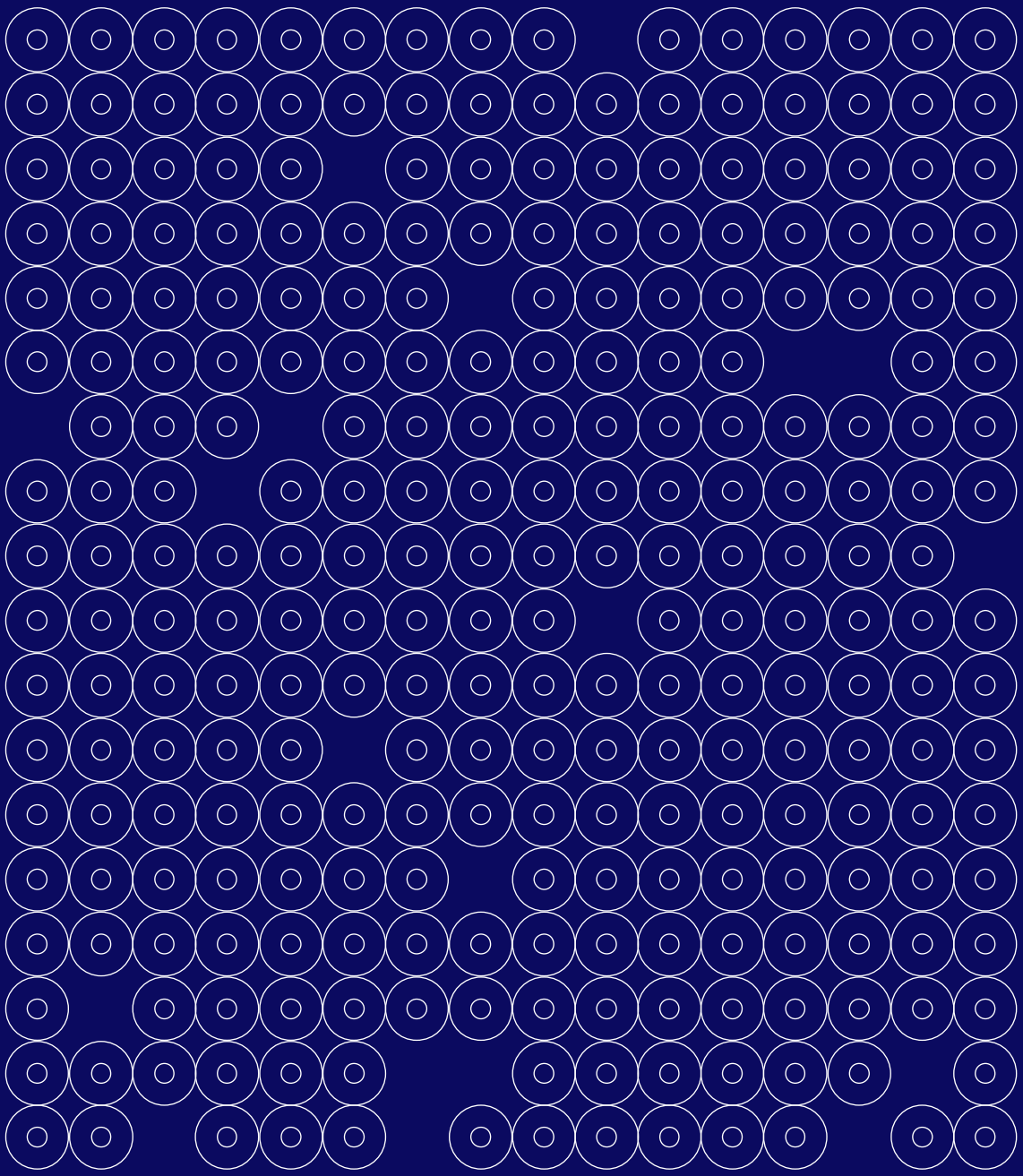
Developing Diagnostic Tools for Drug-Resistant Infections for Human and Animal Health

Online workshop 22 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 in supporting research through funding of 99 projects and 38 networks.

One of the key priorities of the One Health AMR partnership will be to improve the translation of funded projects from academia to industry. Therefore, the aims of the innovation workshop 'Developing Diagnostic Tools for Drug-Resistant Infections for Human and Animal Health' 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 22 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 people registered to attend the meeting, representing twenty-six countries including representatives from Africa, America, Asia, and 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 in AMR diagnostics for humans and animals.

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. Creation of a repository of knowledge in an online platform.
2. Partnering with other stakeholders to provide academics, early entrepreneurs and staff working at knowledge transfer and commercialisation offices translational knowledge. This could include workshops, bootcamps, accelerators, etc. This could

also include learning about the R&D system, value propositions, the facilitation of links with end users and other stakeholders and a mentoring programme.

3. Organising a showcase event to make industry aware of the excellent research that is happening at universities.
4. Projects funded by the partnership should include a clear understanding of the market opportunity, competition, impact, and route to translation. Projects should "begin with the end in mind" at the project planning stage.
5. Work with other funding agencies (national, global, public, and private) to:
   - Facilitate follow-on funding for the projects funded by the One Health AMR partnership.
   - In the human space, the partnership should consider engaging with other funding organisations (for example CARB-X) to align its funding calls for diagnostics to support the needs of the therapeutics and prevention projects.
   - Consider creating challenge-led funding competitions with a potential guarantee of procurement. Themes could/should be discussed with industry.
   - Develop incentives/partnerships to encourage private sector investment.

Introduction

Background and objectives

A partnership on antimicrobial resistance

In 2021, the European Union (EU) launched "Horizon Europe", its framework 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 Horizon Europe. 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 assist 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

- The workshop lasted 3.5 hours and consisted 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 of diagnostic assays.

- The number of participants was kept relatively low (max 50 people) to be able to facilitate the discussion during the breakout sessions (see Agenda in Appendix 1).
- 50 people registered to attend this workshop, including organisers, presenters, academic researchers, industry, national and global funders, and other enabling organisations.
- The workshop included participants from at least 26 countries, including representatives from Europe, America, Africa, and Asia. See figure 1.
- The gender balance was 54% male, 42% female, and 4% preferred not to say. See figure 2.
- Of the organisations present 26% were private sector organisations, 58% were public sector organisations (including academic research centres, government funding agencies, and public hospitals), and 16% were not for profit organisations (including global funders and enabling organisations, some of them actively involved in research).

Europe		**Africa**		**America**		**Asia**	
Austria	1	Burkina Faso	1	Canada	2	India	2
Belgium	1	Congo	1	Uruguay	1	Israel	1
Denmark	1	Libya	1	USA	2	Pakistan	1
France	1	Tanzania	1			Philippines	2
Germany	6	Togo	1				
Italy	1	Tunisia	1				
Netherlands	1	Uganda	1				
Poland	1						
Spain	4						
Sweden	3						
Switzerland	1						
UK	11						

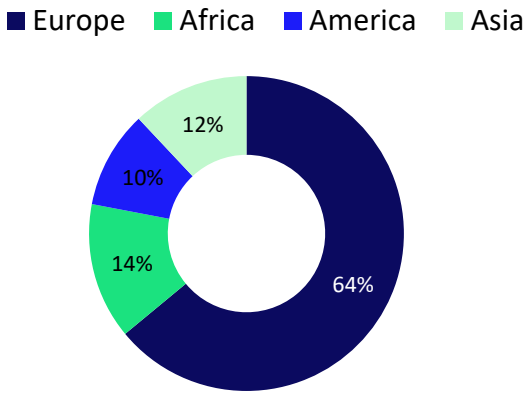

Figure 1. Geographical distribution of the participants (including organisers, presenters, academic researchers, industry, global and national funders, and enabling organisations).

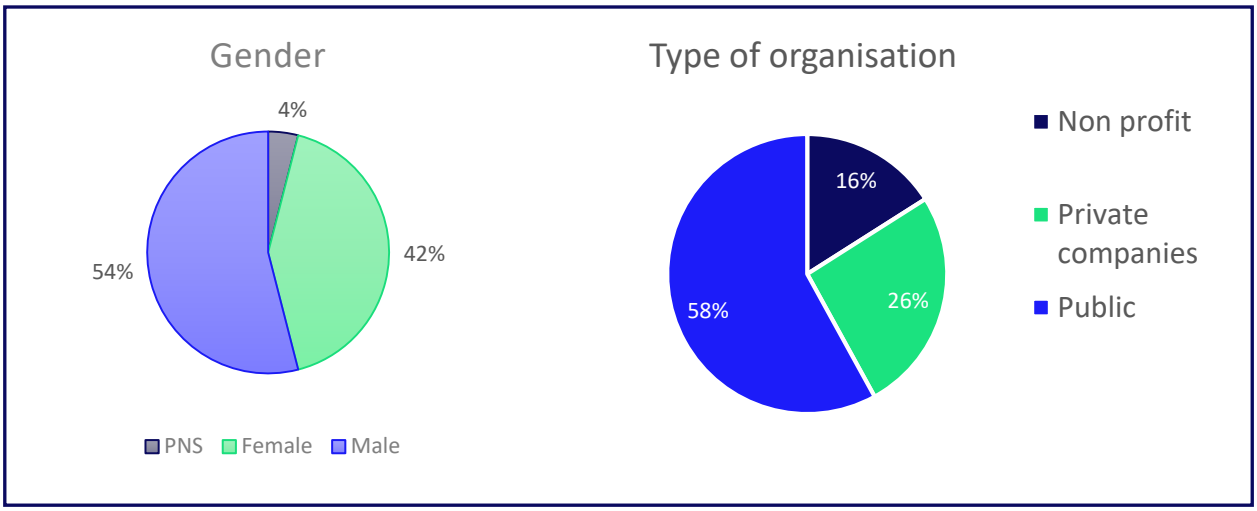

Figure 2. Public organisations include academic research centres, government funding agencies, public hospitals. Not for profit include including global funders, and enabling organisations, some of them actively involved in research.

Workshop sessions

Session 1. Aims and challenges in developing diagnostic tools for drug-resistant Infections in human and animal health.

Presenter: Prof. Till Bachmann, Edinburgh University (UK) and Chair of JPIAMR Scientific Advisory Board.

Till Bachmann introduced the meeting by setting the scene about the gaps and challenges of developing novel diagnostic tools for drug resistant infections for human and animal health.

To date, JPIAMR has invested over €125M and supported 99 projects and 38 networks related to AMR priority topics (Surveillance, Diagnostics, Environment, Therapeutics, Transmission, and Interventions).

In the diagnostic space JPIAMR has invested €5.3M and funded seven research projects nine networks in the areas of:

- Novel or improved diagnostic tools
- Rapid diagnostics and point of care to improve personalised therapies
- Methods to detect AMR in multiple reservoirs
- Identification of barriers for development and rapid implementation of rapid diagnostic tests.

JPIAMR has applied a One Health approach, focusing on the WHO priority pathogens and funding projects and networks with low- and-medium income countries (LMICs).

Till presented a snapshot of the current JPIAMR funded projects and networks in the diagnostic space. He also mentioned that this workshop is included in a series of events preparing the launch of the candidate One Health AMR partnership which will have five research focal areas:

- Diagnostics
- Surveillance
- Transmission and Evolution
- Prevention and Intervention
- Therapeutics

The partnership will also include some cross-cutting themes:

- Social sciences
- Innovation
- Implementation
- Inclusion/diversity

Session 2. Industry's perspective – Learnings from an SME on the translation from academia to industry in the human health space.

Presenter: Dr. Tanya Gottlieb, PhD, MBA, VP Scientific Affairs at MeMed (Israel).

Tanya stated that it is challenging to take innovations from academia to industry. Further challenges exist when attempting to incorporate a commercially viable product into routine care for diagnostic innovations in the AMR space.

MeMed has developed a diagnostic tool that leveraged the host's immune response to infection instead of detecting the pathogen or determining its sensitivity to drugs. This tool helps to determine if a patient has a bacterial or a viral infection, thus preventing the unnecessary prescription of antibiotics for a viral infection.

The key message was **"begin with the end in mind".**

There are five key areas to focus on at the discovery stage to increase the likelihood of successful translation:

1. Define the problem in detail – what information is needed to change clinical practice?
   - Focus on a specific clinical dilemma.
   - Location - where will the test be conducted?
   - Actionability - what turn-around and result presentation are required?
   - Diagnostic gap – what will change clinical practice?
2. Demonstrate solution feasibility.
   - Technical and scientific considerations.
3. Consider steps to patient impact.
   - Workflow constraints in the discovery phase.
   - Clinical and analytical validation – how scalable is the manufacturing?
   - Product development and manufacturing.
   - Regulatory – determining diagnostic performance.
   - Global deployment and reimbursement.
   - Adoption and patient impact.
4. Build a network of partners.
   - Investors, clinical, industry and industry membership associations.
5. Data.
   - High-quality data to support the technology and its performance.

Session 3 Industry's perspective – Views of a large company in the animal health space.

Presenter: Dr. Jeffrey L. Watts, PhD, RM (NRCM) M (ASCP). Research Director of External Innovation. Veterinary Medicine Research and Development at Zoetis (USA).

Diagnostics is a key component of the continuum of care of the animal health system.

- Predict – predispositions based on genetic testing.
- Prevent – through vaccinations, hygiene, and biosecurity.
- Detect – through diagnostics.
- Treat – sick animals using the most effective agents based on diagnostics.

Jeffrey presented the diagnostic R&D process stages (Table 1) and mentioned that before an academic researcher approaches a pharmaceutical company in the veterinary space, it is advisable to understand at what point of the R&D process will their technology enter the system. When an academic approaches a company, it usually takes another 8-12 years of R&D before it becomes a commercial product. Ideally, the academic partner should have all the data to demonstrate proof of concept and be ready to enter the alpha stage. It is also essential to understand the market focus and strengths of the potential industry partner.

Table 1. R&D process stages. Extract from Jeffrey L Watts presentation.

Phase	Stage Gate Deliverables
Proof of Concept	• Demonstrated technical feasibility on key technology and/or addressed critical high-level risks • The design path(s) has been understood, selected, and planned. • Enough data has been generated to give technical confidence the design path(s) selected is likely to succeed.
Alpha	• Demonstrated feasibility of achieving the target profile on the R&D Prototype • The prototype has been characterised and verified according to the approved test plans • Diagnostics (Dx) test design process, draft quality control tests and specification ready to release to manufacturing
Beta	• Successful release of design and process to manufacturing is complete • Verification and validation complete using final produced Device, Dx Test and production ready software in a fully integrated system.
First Production	• Obtained marketing authorisation/licenses for the first markets for regulated Dx test • Obtained all necessary certification documentation for devices • First production placement conducted with key customers
Launch	• Ready to begin sale of the product in target markets • Developed regulatory and marketing strategies for mobilizing the product to all target markets

Jeffrey highlighted various diagnostics evaluation questions that Zoetis uses when they evaluate a new technology from a potential partner.

- Does this opportunity fit current strategy and/or product profiles?
- Please provide a description of technology
- Has any patent application been filed? Has Freedom-to-Operate assessment been conducted?
- What veterinary tests have been developed on this platform?
- What clinical data are available?
- What are the clinical performance specifications (sensitivity and specificity)?
- What is the limit of detection?
- What is the overall time-to-result?
- Is sample preparation/treatment needed?
- What is the current development stage?
- What is the multiplexing limit (number of targets)?
- What sample types has the company tested on this technology?
- What sample volume is needed?
- What is the throughput per run?
- Does the company also have discovery and reagent generation capability?
- Does the company have manufacturing capability? Has the company identified potential contract manufacturing organisations?

In addition to sensitivity and specificity other assay development parameters are also important and should be considered, for example:

- Accuracy – closeness of test result to true value
- Precision – reproducibility of the assay
- Robustness – tolerance to individual analysts
- Ruggedness – tolerance to difference component sourcing

Session 4. Funding landscape

Presenter: Usha Lamichhane, Scientific Programme Officer at the Global AMR R&D Hub (Germany).

Usha 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.

One of their key 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
- Antibacterial agents in clinical development
- Incentives for antibacterial agents

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). Diagnostics attracts around 8% of the total funding, equating to approximately $725 million.

The emphasis on diagnostics changes by sector. In human health, the total investment in diagnostics was 8% of $600 million ($48 million), while in the animal sector, the diagnostic investment was 11% from a total of $66 million ($7.26 million). This shows that there is a significant gap to be filled in the animal sector.

High-income countries (HICs) fund most of the AMR diagnostics R&D. The leading funder is the USA, followed by the European Union, the United Kingdom and Germany. Although the funding is spread worldwide, most funds are invested in HICs. An approximately equal amount of funding goes into academic research and SMEs, and the funding mainly comes from public funding bodies, followed by public-private partnerships.

44% of the total funding in diagnostics focuses on priority pathogens, and of this 82% focuses on high-priority pathogens, particularly in the Mycobacterium species, followed by Neisseria and Salmonella species. By disease, most of the projects focus on tuberculosis (46%), sexually transmitted infections (14%), sepsis (11%), blood stream infections (8%) and urinary tract infections (7%).

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[1]. The report was written by an expert advisory group and estimated the global market potential for therapeutic and diagnostic products representing some of the most significant unmet needs in the AMR field. It identified two priority needs for diagnostics:

- Rapid point of care (PoC) devices to differentiate bacterial from non-bacterial infections
- A diagnostic device that can perform pathogen identification and antibiotic susceptibility testing in one device

The report also presents a forecast up to 2040 on the market potential and quantifies the uncertainty of the commercial estimates and market leader possibilities. It shows that the revenues generated are not attractive for diagnostic developers in the current situation. Incentives for increasing the uptake of diagnostic tools are needed to encourage new developments in this space.

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

Session 5. Round table discussion - funders' perspective.

Chair. Prof Till Bachmann, Edinburgh University (UK).

Panellists:

- Dr. Betsy Wonderly Trainor, CARB-X (USA).
- Dr. Sumithra Subramaniam, Wellcome Trust (UK).
- Dr. Armando Heriazon, IDRC (Canada).

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 (CARB-X)

CARB-X is a global non-profit partnership 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 aims to invest $822 million from 2016 to 2032 to accelerate innovation to address AMR. They target the priority pathogens list of Centers for Disease Control (CDC) and the World Health Organisation (WHO). CARB-X provides non-dilutive funding for early product development after the concept phase until the alpha prototype. Case studies show that some companies that graduated from CARB-X received further investment by public bodies while others received private investment and were acquired by larger companies.

CARB-X applies a "align by design strategy" to their portfolio, ensuring that therapeutics that are coming to market are supported by the corresponding diagnostic tools either to support clinical development or market uptake. In addition to funding, CARB-X provides scientific and business expertise by working with accelerators globally.

The CARB-X diagnostic strategy is firstly to match their therapeutic products in their portfolio and connect those companies with diagnostic companies that already have solutions on the market. If nothing exists and the diagnostic needs of the therapeutic companies are novel, they will look at platform expansion (different instrumentation, new cartridges, and new pathogens can be added to panels), leveraging the existing technologies in the market. Lastly, they will look at developing novel technology if platform expansion is not an option.

Wellcome Trust

Wellcome Trust is a politically independent charitable trust and a global funder focusing on improving various aspects of human health. Their current focus is on infectious diseases, mental health, climate, and health.

Wellcome is investigating how they can better support diagnostics for infectious diseases focusing on LMICs. They also look at common emerging themes across diagnostics, such as regulatory policy and advocacy. They have a One Health approach, for example, infections in the food chain, environmental surveillance and how climate might affect the rates of infections.

Sumithra highlighted some of the work done by the ValueDx project[2], which focuses on accelerating the assessment and implementation of novel diagnostic technologies in healthcare settings.

Wellcome is also supporting studies to speed the uptake of diagnostics in LMICs by improving the validation and evaluation of diagnostic kits in various countries.

International Development Research Centre (IDRC)

IDRC is a crown corporation, part of Canada's foreign affairs and development efforts. It provides research funding mainly in developing countries, as well as advice, training, and knowledge sharing to improve the life of people in these countries. IDRC focuses on climate resilient food systems, global health, education in science, democratic and inclusive governance, and sustainable inclusive economics. All IDRC calls have an LMIC component and gender considerations.

In animal health IDRC has two programmes:

- Vaccine innovation fund in partnership with Global Affairs Canada and the Bill and Melinda Gates foundation.
- Innovative veterinary solutions for AMR in partnership with the Global AMR Innovation Fund (GAMRIF) from the UK Department of Health and Social Care.

IDRC's animal project portfolio includes targeting 26 diseases in ruminants, poultry, and swine in 34 countries.

Highlights of the panel discussion session

One Health projects are challenging because they need to integrate all the multidisciplinary expertise required (human, animal, and environmental health).

Collaboration with other funders and stakeholders is vital to support the continuum of translation, implementation, and adoption of solutions. For this, it is necessary to understand the funding focus of each of the other funding partners.

[2] *https://www.value-dx.eu/index.php/what-is-value-dx/*

Many funders now have a One Health approach and focus on gender balance. There is an increased focus on the impact of climate change on human health.

Some national funders commented that it is essential to follow up with funded projects in early development and continue supporting them to reach the market. This could help to prepare for future outbreaks.

The Covid-19 pandemic helped to bring diagnostics to the public and funders' attention, at least in HICs.

During the Covid-19 pandemic, a few countries, including France, Germany, and the UK, made significant funding available to develop diagnostic tools for Sars-CoV-2. Also, the BEAM alliance reported that during the Covid-19 pandemic, some of their member companies developing diagnostics for AMR moved into the Covid-19 space. This brings some hope that some companies will adapt their solutions to fight AMR in the future.

It was also highlighted that the Longitude Prize competition is still ongoing, and participants were encouraged to take part and share this information.

Some diagnostic companies in the AMR space mentioned that the Covid-19 pandemic represented a significant setback, as the acquisition and adoption of rapid diagnostic tools for AMR stopped.

In addition to developing technology, adoption and implementation are crucially important. The UK is exploring business models to support AMR companies all the way to commercial adoption. However, it was noted that this is challenging and will not happen in the short term.

It was also mentioned that various novel diagnostic technologies were developed during the Covid-19 pandemic. However, it is likely that some of these new technologies will not be taken forward as the solutions widely adopted during the Covid-19 pandemic were the old solutions, such as polymerase chain reaction (PCR) and lateral flow tests.

Could a challenge-led approach be used to help to continue developing and implanting the adoption of these technologies?

IDRC provides regulatory and quality assurance training and support, which are essential to implementing solutions. It is also necessary to understand the market potential, value chain, and impact of a given technology. The empowerment of women in the value chain plays a vital role in adopting technologies in African countries.

To understand the real burden of AMR, it is necessary to look at the human, animal and environmental context, such as transmission routes. In the future, diagnostic tools could help predict how and when pathogen X might enter the human population. Therefore, connecting the entire pipeline from surveillance to data capture, analysis, and integration is crucial.

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 discussed 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 systems worldwide geared up to support the implementation of diagnostics in human and animal healthcare? What would be the major challenges?
- What do we need to solve this?
- How can the candidate One Health AMR partnership help in these actions?
- What can we learn from the Covid-19 pandemic regarding the development and implementation of rapid diagnostics?

Although there are some differences between the human and animal health, in terms of improving the translation from academia to industry, the challenges are quite similar and the solutions applicable to both sectors.

1. Adoption

The key challenge is not necessarily moving a project from academia to industry but the adoption of novel diagnostics once they have been developed.

- Need to change the "not invented here opinion".
- Flow of money between the health system and the lab is a challenge.
- Silos within the health system are an issue.
- There is a need to educate the end user on novel technologies.
- There is a lack of awareness around AMR and the importance of controlling the use of antibiotics especially in the animal husbandry.
- Economic constrains of the use of diagnostics which adds to the cost and reduce revenue margins, vs randomly use of antibiotics.
- Cost effectiveness, sensitivity, specificity, robustness etc., in specific settings must be considered.
- In some instances, a change in culture is needed (both in the human and animal space).
- Economic drivers beyond the end user need to be considered, e.g., in the case of animal health it is necessary to consider production systems.

Solution(s)

- Exploring alternative business cases and models such as developing novel antibiotics alongside diagnostic tools to support clinical testing and adoption. (See comment above on CARB-X "align by design" strategy). This was also a recommendation in the policy report "Ensuring AMR Diagnostic Innovation & Uptake" from the Global AMR R&D Hub[3]. Currently, there is not much support from the developers. It is necessary to ensure alignment of economic drivers from both therapeutics and diagnostic companies. Diagnostic in the context of a

[3] *https://globalamrhub.org/wp-content/uploads/2021/08/Dx-Policy-Brief_FINAL-1.pdf*

therapeutic tends to make projects and the translational pathway more expensive. Diagnostic companies will not usually have experience or links to therapy field.
- Develop a clinical experience programme to prevent repeating evidence that has already been generated.
- Money could be spent on procurement plans within healthcare and systems.
- Organise meetings/workshops with academics, end users, industry and other stakeholders to ensure that academic research is directed towards diagnostics that would actually be used (both for human and animal health).
- Understand and be able to communicate the added value of a diagnostic test to the customer (pet owner or food industry, clinician, etc) especially if they are the ones paying for the test.
- The market for companion animal diagnostics should not be underestimated. Research has shown that people are much more accepting of higher prices for the treatment of their companion animals. This could be used to balance the development costs and perhaps use in production animals.

2. Sample access

- Difficult to access to the right samples.

Solution(s)

- Biobanks need to be more geared towards commercial needs.

3. Funding and prizes

- A key limitation is the duration of funding for academic research projects. At the moment, close to the end of the project academic researchers need to start looking for new funding and if it is not found quickly it is not easy to continue focusing 100% on this project after the funding has finished. Usually this is the valley of death when it is too early for industry funding but doesn't fall in the academic sphere either.
- Public and private funding for early-stage projects for diagnostic developers is needed.
- Private sector funding should be encouraged.

Solution(s)

- Having long term funding or connect various types of funding to ensure follow up funding for successful projects.
- Ensure that funding covers more than bacterial pathogens. Include non-bacterial pathogens.
- Develop incentives/partnerships to encourage private sector investment
- The Longitude prize challenge model was seen as being useful. It was recognised as globally instrumental. Even if there is only one winner, the process was useful to build a pipeline.
- Consider creating challenge-led funding competitions with a guarantee of some procurement. Themes could/should be discussed with industry.

4. Specific settings

- Move away from point of care to point of need (learning from Covid-19).

- Need to validate and perform trials in the settings in which they will be used. For example, for LMICs, it is necessary to consider levels of humidity, high temperatures which may mean outside of an air condition setting and the diagnostic platform may struggle to perform. Extreme temperatures may become more common in other geographies due to the climate change. Even the same pathogen may differ in the way in which symptoms rise and the outcomes associated with that may be very different depending on the setting in which the diagnostic is deployed.
- Lack of target product profiles is an issue for LMICs and developed economies.

Solution(s)

- Consider point of need, where the patient is (instead of point of care) to allow rapid diagnosis allowing the patient and caregiver to take rapid and appropriate action.
- Testing criteria were significantly relaxed during the pandemic. Public acceptance and familiarity with diagnostic assays have improved due to the pandemic (learning from Covid-19 pandemic).

5. Improving the use of antibiotics

- Overuse of antibiotics in LMICs is a serious issue. More needs to be done to develop cost effective diagnostic platforms.

Solution(s)

- Regulate antibiotic use without better testing (everywhere not only in LMICs)

6. Regulation

- Toxicity awareness is now more common

Solution(s)

- Diagnostic tools can be used to alleviate toxicity concerns.

7. Capacity building. "Begin with the end in mind"

- 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. Factors that need to be considered are:
  - Understanding the entire diagnostics R&D system (see Session 3), including the time and investment that is needed to develop and commercialise a diagnostic solution. It is advisable to understand at what point of R&D process, their technology is entering the system.
  - Understand the user (laboratory technician, clinician, general public, farmer, veterinarian, etc.), including issues related to training and ease of use.
  - The setting in which diagnostic test is going to be used.
  - Create a good value proposition – understand the purchaser view and the associated economics drivers.
  - The regulatory requirements which will inform either a licencing discussion or the formation of a spin out company

- Awareness that academia and industry have different drivers which are not necessarily aligned. Industry can still publish information that doesn't affect the IP position of the company however in many cases, in industry publications have low value unless they help to market a product.
- Understand the way that information packages are required to be able to fit into the industry R&D process.
- Understand the importance of traceability
- Understand your competition especially in more mature markets. How your solution compares with the current practice and is it cost effective?
- Before starting a project, it is important to have a clear understanding of the goal, potential impact, and outcome of the research. "Begin with the end in mind" but much earlier.
- Technology transfer and commercialisation offices at universities can sometimes be very aggressive with their terms and get in the way of establishing an industry-academic collaboration.

Solution(s)

- 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. What the advantages of each case will be.
- Consider a 6-month placement exchange programme between academia and industry (swap). It will allow academics to learn about the different groups involved in industrial R&D (quality control, marketing, etc) and industry and academia to exchange knowledge.
- Create an online repository of knowledge that can be accessed by everyone, everywhere. This document could include a check list of requirements needed before exploring licensing or other commercial deals with industry.
- Create end user workshops on specific themes/challenges to understand the factors that may affect the adoption of a solution. In the veterinary space it would be important to include other stakeholders such involved in the food production system.
- Create a platform for academics and industry to share ideas, although we will need to be mindful of IP protection.
- 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.
- Organising a showcase event to make industry aware of the excellent research that is happening at universities, which might help to start early discussions and collaborations.
- Technology transfer and commercialisation offices at universities could play a more active role helping academics to understand industry needs, strengths, focus and opportunities at an early stage in the project and not at the point where IP has been registered/protected.

8. Other important considerations not necessarily aligned with the use of diagnostics.

Need to reduce the antimicrobial use.

- In the animal sector, this could be achieved by improving animal husbandry settings to improve animal welfare and improve biosecurity.
- In the human space preventive measures vaccines and education to improve hygiene practices.

Recommendations

This section includes actions that the candidate One Health AMR Partnership should consider to improve the translation of their funded projects from academic research to industry.

1. Creation of a repository of knowledge in an online platform.
2. Partner with other stakeholders to provide academics, early entrepreneurs and staff working at knowledge transfer and commercialisation offices translational knowledge. This could include workshops, bootcamps, accelerators, etc. This could also include learning about the R&D system, value propositions, the facilitation of links with end users and other stakeholders and a mentoring programme.
3. Organising a showcase event to make industry aware of the excellent research that is happening at universities.
4. Projects funded by the partnership should include a clear understanding of the market opportunity, competition, impact, and route to translation. Projects should "Begin with the end in mind" at the project planning stage.
5. Work with other funding agencies (national, global, public, and private) to:
   - Facilitate follow-on funding for the projects funded by the One Health AMR partnership.
   - In the human space, the partnership should consider engaging with other funding organisations (for example CARB-X) to align its funding calls for diagnostics to support the needs of the therapeutics and prevention projects.
   - Consider creating challenge-led funding competitions with a potential guarantee of procurement. Themes could/should be discussed with industry.
   - Develop incentives/partnerships to encourage private sector investment.

Appendix I. Agenda

JPIAMR Innovation Workshop: Developing Diagnostic Tools for Drug-Resistant Infections for Human and Animal Health.

Date: 22nd June 2022
Time: 13.30 - 17.00 CEST / 12.30 - 16.00 BST
Platform: Zoom meeting

Time (CEST)		
13.30	Welcome and aims of the meeting	Gabriela Juarez Martinez, Innovate UK KTN
13.40	JPIAMR aims and challenges in developing new diagnostics for drug-resistant infections	Till Bachmann, University of Edinburgh
13.55 14.10	Industry's perspective – Learnings from collaborations with research institutions.	Tanya Gottlieb, MeMed Jeff Watts, Zoetis
14.25	Breakout session 1: Gaps, barriers, and opportunities in the translation of research of diagnostic tools for drug resistant infections.	
15.10	Summary of the discussion	All
15.20	Break	
15.30	Funding landscape	Usha Lamichhane, Global AMR R&D Hub
15.45	Roundtable Discussion – Funders' perspective	Chair: Till Bachmann, University of Edinburgh. Betsy Wonderly Trainor, CARBX Sumithra Subramaniam, Wellcome Trust Armando Heriazon, IDRC
16.50	Closing remarks and next steps	Gabriela Juarez Martinez, Innovate UK KTN

Appendix II. Biographies

Presenters

Armando Heriazon (IDRC). Doctor in Veterinary Medicine from the National Autonomous University of Mexico; MSc and PhD in Immunogenetics from the University of Guelph; and a MBA from the University of Prince Edward Island. Worked as a veterinary practitioner and for the Pharmaceutical Industry in diverse areas, including technical services and R&D in vaccine development. Has been working for IDRC for four years in the Animal Health division.

Betsy Wonderly Trainor (CARB-X). Alliance Director for the Diagnostics portfolio at CARB-X. Prior to joining CARB-X three years ago, Betsy worked in the IVD industry supporting product development and commercialization activities as well as with non-profit organizations like FIND and the WHO to support product validation and implementation efforts for infectious disease diagnostics.

Jeffrey L Watts, (Zoetis). Research Director, External Innovation. Primary responsibilities include the identification of novel substrate through collaboration with external institutions that will support the development of novel, veterinary spectrum specific agents. Additional responsibilities include the development of policies and strategies to advance the responsible use of anti-infectives in veterinary medicine at the global and regional levels. He holds a Bs Ms in Microbiology and a PhD in Medical Microbiology and Bacteriology. He has over 30 years of experience in the animal health pharmaceutical industry.

Sumithra Subramaniam (Wellcome Trust). Senior Research Manager for Diagnostics in the Infectious looking at how the Wellcome Trust can best invest in diagnostics. Previously she was part of the basic science research team. She has worked in diagnostics in the NHS and ran a programme at CRUK to embed molecular testing into the cancer pathway to allow patients to access precision therapies. She has a Bs in Biomedical Sciences from the University of Manchester, Ms in Medical Immunology form Kings College London and a PhD in Cutaneous Immunology and Allergy from the University of Oxford.

Tanya Gottlieb (MeMed). Tanya has over 20 years of experience in academia and biotech, specializing in building and cultivating international collaborations and securing non-dilutive financing. Before joining MeMed, Tanya was Director of Business Development at BiondVax Pharmaceuticals Ltd (NASDAQ: BVXV), an innovative start-up developing a universal flu vaccine, where she initiated collaborations with the National Institute of Health (US) and European Commission. Prior to that, Tanya served as an independent consultant for key opinion leaders in Israel and Europe, helping to maximize their impact in the field and win awards. Tanya conducted her postdoctoral research at the Weizmann Institute of Science, Israel and the Fred Hutchinson Cancer Research Center in Seattle, WA, USA. Tanya holds a B.A. in Natural Sciences and Ph.D. from Cambridge University, UK. and an MBA from the Technion, Israel. She is the co-

author of over 20 peer reviewed publications and the recipient of multiple awards, including the prestigious Royal Society (UK)-Israel Academy Fellowship.

Till Bachmann (University of Edinburgh). Chair of Molecular Diagnostics and Infection and the Deputy Head of Infection Medicine at the Deanery of Biomedical Sciences at Edinburgh Medical School, University of Edinburgh. Coordinator of the UK-India project 'DOSA - Diagnostics for One Health and User Driven Solutions for AMR', and the JPIAMR-VRI Network AMR Dx Global, succeeding the JPIAMR Transnational Working Group on Rapid Diagnostic Tests. Till is the AMR Strategy Lead for Edinburgh Infectious Diseases and the founder of Edinburgh AMR Forum. Till fulfils a range of industrial and institutional advisory roles worldwide. As such he is Chair of the Scientific Advisory Board of the Joint Programming Initiative on Antimicrobial Resistance (JPIAMR), judge for the Longitude Prize on Antibiotics, Advisor for BIRAC (Biotechnology Industry Research Assistance Council) Mission of the Department of Biotechnology of the Indian Government, CARB-X (Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator), German Institute for Bioprocessing and Analytical Measurement Techniques, World Health Organization (WHO) and One Health Quadripartite (Food and Agriculture Organization of the United Nations (FAO), World Organisation for Animal Health (OIE), United Nations Environment Programme (UNEP) and WHO).

Usha Lamichhane (Global AMR R&D Hub). Scientific Programme Officer. Previous roles part of the health team of Young Leaders for Health, a not-for-profit organisation nurturing the next generation of leaders in public and global health and researcher at Jacobs University in Bremen. She has a Batchelor degree in Biotechnology, MSc in Molecular Life Sciences and a post-graduate degree in Public and International Health.

Organisers

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 Plant (Swedish Research Council). She has a PhD in Microbiology from the University of New South Wales in Australia and a research background in the field of bacterial pathogenesis and immunity from the Nestlé Research Centre, University of Melbourne, and Karolinska Institute. She 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, has had roles as National

Contact Point for Health and Programme Committee Expert for Widening and ERA in the Horizon Europe framework programme and 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), 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 ERA-NET ICRAD, in the JPIAMR, In the JPI HDHL and in the CSA DESIGN OH AMR for which she is in charge of coordinating the drafting of the Strategic Research and Innovation Agenda of the candidate One Health AMR partnership.

Terry O' Neill (Innovate UK KTN) 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.