INNOVATE UK
GLOBAL EXPERT MISSION

Anti-Microbial Resistance Germany | 2018

Confidential

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Preface

To help UK businesses become truly global enterprises through strategic international innovation collaboration, Innovate UK[1] launched its Global Expert Missions in October 2017. Delivered by the Knowledge Transfer Network (KTN)[2] in partnership with the UK Science and Innovation Network (SIN), the Expert Missions provide an expert-led evidence base to strengthen Innovate UK's global investment strategy: how and where it should invest to create UK business opportunities in partnerships with key economies.

Each Global Expert Mission will have selected representation from UK business, policy and research community, with the following objectives:

1. Gather market insights and build expert foresights on new and emerging innovation sectors.
2. Identify opportunities for international collaboration.
3. Build a portfolio of technological and business priorities that will elevate the UK as the 'Partner of Choice' in future innovation partnerships with global partners.
4. Facilitate international dialogues for the UK business community.
5. Align innovation policy and unlock regulatory barriers for future partnerships.

Innovate UK's Global Expert Missions programme is one of its most important tools to support the UK's Industrial Strategy's ambition and for the UK to be the international partner of choice for science and innovation. Global collaborations are crucial in meeting the Industrial Strategy's Grand Challenges.

In May 2019, an Expert Mission travelled to Germany. The UK delegation met with German federal officials, academics and commercial entities gaining exposure to some 16 antimicrobial resistance (AMR) related organisations and learning about many programmes that could directly benefit from collaboration and joint ventures with organisations involved in AMR in the UK.

In this publication, we share the information and insights gathered during the delegation's time in Germany. It is written from the perspective of how the collaboration may add to curbing AMR in both countries whilst also exploring opportunities for increased innovation and economic development.

[1] www.gov.uk/government/organisations/innovate-uk
[2] www.ktn-uk.org

1 Summary

The Global Expert Mission to Germany on AMR left the UK delegation with the impression that the UK and Germany have much common ground when it comes to combating the escalating global threat. The countries clearly share the concerns, pinpoint the relevance of innovation and agree that joining forces in combating AMR is of key importance.

Overall Germany has the same perception of the challenges offered by AMR. Meanwhile it must be concluded that there are substantial differences when trying to curb AMR. The German AMR strategy ('DART 2020[3]') stresses the importance of 'measure and improve treatment' whereas the UK's long-term strategy focusses on 'contain and control' which sets the emphasis on 'infection prevention, stewardship and innovation'[4].

Probably the most striking difference between Germany and the UK is the absence of an overall German national approach where it comes to tackling AMR. Admittedly, there is the national strategy DART but when performing the strategy the federal republic Germany has to deal with 16 autonomous, federal states which implement the national strategy differently. It must be realized that the federal states differ substantially in financial strength and innovation potential and compete for the same national funding. In addition, Germany lacks a national, single point of entry for AMR.

It is evident that Germany, although gradually expanding its geographic scope when it comes to activities related to AMR, has a rather inward focus. In contrast, the UK assumes a much more international approach (and takes related responsibilities), demonstrated by its strategy of tackling AMR in many Low and Middle Income Countries (LMIC's).

This Global Expert Mission has defined a considerable number of objectives and related, concrete follow-up actions. The objectives start from the principle that they add to the (global) curbing of AMR. In addition, they take into account the relative strengths and weaknesses of both countries.

In the *short term* the Global Expert Mission recommends the below as follow-up actions:

I. Organising a UK-German round table to improve infection prevention and stewardship in LMIC's and Germany
II. Organising a UK mission to Germany to capitalise on the big data expertise and infrastructure in the UK
III. Inviting Germany for a mission to come to the UK to accelerate (co-)development and implementation of novel diagnostics in the UK.
IV. Setting up a UK-German feasibility study to explore the potential of 'companion diagnostics'

[3] DART: Deutsche Antibioka Resistenz Strategie
[4] Contained and controlled: The Uk's 20-year vision for antimicrobial resistance

V. Organising a German mission to UK to accelerate (co-)development of novel therapeutics and to allow both nations to understand the technical capabilities in both nations to support this.
VI. Otherwise profile the UK capabilities when it comes to AMR in Germany.

The UK delegation felt it would be valuable to further intertwine German and UK networks of public and private stakeholders involved in AMR. This may well be realised by organising a UK envoy to one or more of the annual AMR conferences organised in Germany and by extensively promoting the UK during the events.

In the *longer term* a joint UK-German call to enhance applied and above all translational research related to AMR in Germany and the UK will further strengthen collaboration between the two countries and add to curbing AMR.

GEM Anti-Microbial Resistance Germany in the Brittish Embassy in Berlin

2 Anti-Microbial Resistance

Anti-microbial resistance (AMR) develops when bacteria, fungi, or viruses are exposed to antibiotics, antifungals or antivirals. As a result, the antimicrobials become ineffective and infections may persist in the body, increasing the risk of spread to others[5]. In addition, medical interventions including surgery, caesarian sections, chemotherapy and stem cell therapy may become impossible.
AMR is considered the biggest global threat of Health and Food Safety. It is estimated that AMR causes at least 700,000 casualties per year with the low- and middle income countries (LMIC's) bearing the harshest burdens. More recent recalculations suggest substantially higher numbers. According to the 'Review on Antimicrobial Resistance' by Jim O'Neill we may face some 10,000,000 casualties per year in 2050 with cumulative GDP loss of $ 100 trillion[6]. Without AMR containment, the Sustainable Development Goals for 2030—such as ending poverty, ending hunger, ensuring healthy lives, reducing inequality, and revitalizing global development partnerships—are less likely to be achieved. The impacts of AMR on poverty are particularly concerning. In a high AMR-impact scenario, an additional 24 million people would be forced into extreme poverty by 2030. Most of the increase of AMR would occur in low-income countries[7].

"Planet earth faces the very real threat of having to survive in a 'post-antibiotic' era in which there are few, if any, antibiotics which effectively and affordably cure infections"[8].

2.1 AMR in 10 statements

Antimicrobial resistance is a complex, multifaceted societal and economic challenge comparable with other global challenges like climate change.

In short AMR can be described by means of 10 rule-of-thumb statements:

1. **AMR is a global challenge** affecting all countries around the globe and potentially impacting everybody: young and old, healthy and diseased. As a result of traveling and food transports AMR easily further spreads around the globe.

2. **AMR is a hidden and likely underestimated threat** as infectious diseases may not always be diagnosed, let it be that the causing microorganism has been identified and its antibiotic resistance profile determined. And, if properly diagnosed at all, the patient data may not always be documented and communicated to the relevant health authorities: there is no standardised system for recording the prevalence of AMR deaths.

[5] https://www.who.int/en/news-room/fact-sheets/detail/antimicrobial-resistance
[6] https://amr-review.org/
[7] http://documents.worldbank.org/curated/en/455311493396671601/pdf/executive-summary.pdf
[8] https://www.daghammarskjold.se/publication/antimicrobial-resistance-and-sustainable-development-a-planetary-threat-but-a-financing-orphan/

3. **Lowering the use of antimicrobials** is fine but does not provide the ultimate solution as infectious diseases will occur more frequently and even give rise to novel outbreaks. In countries where antibiotics are difficult to obtain and/or unaffordable the chances on epidemics substantially increase[9].

4. **AMR prevents the effective treatment of infectious diseases but also complicates medical treatments** where antibiotics are used on a routine basis like surgery, chemotherapy and stem cell therapy.

5. **AMR comprises resistance bacteria and also viruses, fungi, yeasts and parasites.** Antibiotic resistance in bacteria provides the biggest health and economic problems. Recent outbreaks of resistant fungi (azole-resistant Aspergillus[10] and multidrug resistant Candida[11]) show that also these microorganisms increasingly threaten public health.

6. **AMR so far has developed against all commercially available antibiotics**. Resistant bacteria were found within months or years after the introduction and sometimes even before commercial introduction. Some new antimicrobial strategies (may) claim that they will not result in resistant microorganisms.

7. **The current pipelines of novel antibiotics is pretty empty** whereas there is a constant need for novel antimicrobial products and alternative strategies. The major reasons for this are the lack of a solid business case for involved pharma companies and the fact that the low hanging fruit of promising compounds has clearly been picked.

8. **AMR at a global scale is escalating** whereby the LMIC's bear the harshest burdens in terms of fatalities, loss of livestock and economic losses. There are indications that climate change, especially observed in these LMIC's, will further increase the impact of AMR.

9. **AMR is considered a OneHealth challenge** involving both human health, animal health and the environment but also related industries such as the Agri and Food (dairy, meat) sectors, the water sector and also the tourism sector.

10. **There is not one single solution to AMR.** AMR can only be restrained and contained by the global implementation of the 'key strategies'.

2.2 Key strategies to curb AMR

Both international and national level action plans have been set up by organisations like the World Health Organisation (WHO), Food and Agriculture Organisation (FAO), European Centre for Disease Prevention and Control (ECDC), the US Center for Disease Control and Prevention (CDC) and others to fight AMR. These plans have five underlying 'key strategies' in common:

[9] https://cddep.org/wp-content/uploads/2019/04/AccessBarrierstoAntibiotics_CDDEP_FINAL.pdf
[10] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4706635/
[11] https://www.cdc.gov/fungal/candida-auris/index.html

A. **Improving the prevention of infectious diseases** by raising more awareness, improving hygiene and sanitation, and by vaccination.

B. **Extending the implementation of antibiotics stewardship** including the mandatory prescription of antimicrobials for human and veterinary use, refraining from using antibiotics as animal growth enhancers and prohibiting the free sale of antibiotics as occurs in some of the LMIC's.

C. **Developing and applying improved molecular microbiological diagnostics** for both microbial species identification as well as antimicrobial susceptibility testing and (hopefully) resulting in better, more selective and more justified prescription of the appropriate antimicrobial products.

D. **Developing new (classes of) antibiotics** and other antimicrobial products to which no resistance exists as yet. This strategy includes the reuse of older antibiotics, revitalization of previously written-off antibiotics as well as the registration of existing commercially available antibiotics for novel indications.

E. **Developing alternative antimicrobial strategies** which pave the way to entirely new therapeutic approaches to treat bacteria and other microorganisms such as phage therapy, CRISP-CAS, nanomaterials, the use of natural products as well as other strategies.

2.3 The AMR landscape

AMR is increasingly gaining global attention for obvious reasons. A growing number of organizations is also involved in curbing the escalating threat. However, there is no such thing as an 'AMR sector' and likewise one can't speak of 'innovations in AMR'. In fact many public and private organisations can be, should be or have already been involved in one or more of the five above mentioned key strategies. These organizations may be (and should be) involved at separate stages and in very different ways. This can best be illustrated with some examples:

- Authorities are involved in setting guidelines for infection prevention whereas the actual prevention should take place within hospitals and other healthcare centres.
- Academia is involved in fundamental research for novel antimicrobials whereas big pharma may ultimately develop, register, produce and market the products. For the clinical development part, hospitals are involved.
- Funding organisations and programs provide the means for basic research at universities which is needed for the development of novel diagnostic tools whereas start-up's, SME's and multinational companies are involved in ultimate commercialisation.

Target group / Key strategy	A	B	C	D	E
	Improved Prevention	*Improved Stewardship*	*Improved Microbial Diagnostics*	*Novel Antimicrobials*	*Alternative Strategies*
Authorities					
Healthcare centers					
Academia & Research Centers					
Pharma industry					
Diagnostics industry					
Funding organizations					

Table 1; Organisations involved in curbing AMR

2.4 The UK and AMR

AMR is a serious threat to the public health in the UK. NHS England's Chief Medical Officer, Professor Dame Sally Davies, has reported that antibiotic resistance kills 5,000 people in the UK each year. Yet at least 12,000 people in the UK are likely dying each year just from drug-resistant sepsis[12].

2.4.1 Contained and controlled: The UK's 20-year vision for AMR

According to its vision '*Contained and controlled: The UK's 20-year vision for antimicrobial resistance*' the UK is determined to sustain its efforts in combatting resistance, taking local, national and global 'One-Health' approaches across humans, animals, the environment and food, in line with global ambitions and in collaboration with other nations, partners and the international community.

In its vision, stakeholders at local, national and global levels are collectively strengthening policy and practice, ever improving understanding through research and surveillance, developing effective regulation and advocacy to contain and control resistance. The UK contributes to the global effort through:

1. **A lower burden of infection, better treatment of resistant infections**, and minimised transmission in communities, the NHS, farms, the environment and all other settings.
2. **Optimal use of antimicrobials and good stewardship** across all sectors, including access to safe and effective medicines that have been manufactured responsibly for all who need them; achieving and maintaining usage levels by sector as good as the best countries in the world where comparable data are available.
3. **New diagnostics, therapies, vaccines and interventions** in use, and a full AMR research and development pipeline for antimicrobials, alternatives, diagnostics, vaccines and infection prevention across all sectors; with access to new and old technologies for all[13].

2.4.2 Tackling AMR 2019-2024

The action plan '*Tackling AMR 2019-2024*' is structured using the United Nation's ad-hoc Interagency Framework for Action on AMR and sets out the need for action in 15 areas, together with what is done domestically and how it is supporting global action in each area. The UK will work with other countries to help build this as a blue print for its own plans[14].

The plan has ultimately been designed to ensure progress towards its 20-year vision on AMR, in which resistance is effectively contained and controlled. It focuses on three key ways of tackling AMR:

1. Reducing need for, and unintentional exposure to, antimicrobials
2. Optimizing use of antimicrobials
3. Investing in innovation, supply and access.

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[12] https://www.thebureauinvestigates.com/stories/2016-12-11/superbugs-killing-twice-as-many-people-as-government-says

[13] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/773065/uk-20-year-vision-for-antimicrobial-resistance.pdf

[14] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/784894/UK_AMR_5_year_national_action_plan.pdf

The previous UK 5-year AMR strategy 2013-2018 brought together 21 research funders, including the UK Research and Innovation Councils, government departments, devolved administrations and charities. Also:

1. It has identified four key research themes to target investments:
    - Understanding resistant bacteria
    - Accelerating therapeutic and diagnostics development
    - Understanding real world interactions
    - Behaviour within and beyond the healthcare setting
2. A cross UKRI Council, an AMR initiative was established
3. Some 78 interdisciplinary projects were supported with a total commitment of circa £44M
4. In recognition of the global dimension of AMR, approximately £41M was committed to support projects in partnership with members of the EU Joint Programming Initiative in AMR (JPIAMR), with emerging economies, and with LMIC's.

Under the previous AMR strategy Innovate UK have invested over £12M in more than 60 companies to develop new antimicrobial therapies and over £9M in more than 70 companies to develop new diagnostic capabilities.

Both the 20-year vision and five-year plan have been developed collaboratively across diverse government agencies, working with governments in Scotland and Wales, the administration in Northern Ireland, the NHS, and animal health and welfare agencies.
The UK Catapult centres[15] are involved in research related to AMR[16] and work together with renowned organisations like the British Society for Antimicrobial Chemotherapy (BSAC[17]) and the AMR Centre in Alderley Park[18].

2.4.3 Research through Department of Health and Social Care

The Department is investing over £1 billion a year in health research through the National Institute for Health Research (NIHR). The NIHR supports a wide portfolio of research on antimicrobial resistance (AMR) through various funding streams. In the United Kingdom, investment includes £32 million of capital funding to support AMR research, £19.1 million for AMR research at four NIHR Biomedical Research Centres, and £8.8 million for two NIHR Health Protection Research Units on Healthcare Associated Infections and Antimicrobial Resistance.

The NIHR also supports research into AMR in low and middle-income countries (LMICs), with official development assistance (ODA) funding through the NIHR Global Health Research programme. Investment includes support for the NIHR Global Health Research Unit on Genomic Surveillance of Antimicrobial Resistance, and the NIHR Global Health Research Group on Genomic Surveillance of Malaria in West Africa.

[15] https://catapult.org.uk/
[16] https://md.catapult.org.uk/next-generation-antibiotics-2018-the-presentations/
[17] http://www.bsac.org.uk/
[18] https://www.amrcentre.com/

Working through partnerships with other UK funders, the NIHR Global Health Research programme also supports cross-Research Council initiatives including one led by the Medical Research Council for research into AMR in a global context, and another led by the Economic and Social Research Council to expand understanding of how behaviour within and beyond the healthcare system impacts on AMR.

In addition, the Department has allocated over £50 million of ODA over five years to AMR research through the Global AMR Innovation Fund. This research is delivered through a range of mechanisms and delivery partners, including research councils such as the Biotechnology and Biological Sciences Research Council and Innovate UK, and international partners including the Wellcome Trust, Bill and Melinda Gates Foundation, the United States and German governments, and Canada's International Development Research Centre.

2.5 Germany and AMR

In Germany, each year between 400,000 and 600,000 people become infected with pathogens in connection with inpatient medical treatment, and 10,000 to 15,000 die. Around a third of these infections could be avoided if suitable measures were taken. Resistant pathogens play a particularly important role here, since the treatment options are limited. It is not only the incorrect use of antibiotics in human and veterinary medicine that accelerates the development of resistance in Germany. Inadequate hygiene measures and, not least, commerce and tourism also help to spread resistant pathogens.
With the German AMR Strategy (DART), the German Federal Government presented a concept national strategy in 2008, which aimed at reducing the further development and spread of antibiotic resistance. DART contains a number of measures for recognising, averting, and combatting antibiotic resistance in Germany. The current situation in Germany shows that antibiotic resistance is still not being tackled with the necessary urgency and awareness of the problem still needs to be improved. The revised DART must clearly help here.

2.5.1 Deutsche Antibiotika Resistenz Strategie ('DART')[19]

The German AMR Strategy (DART) in 2008 contains a number of measures in the areas of human and veterinary medicine for recognising, averting, and combatting antibiotic resistance in Germany. The central goal is the reduction of antibiotic resistance by:

[19] https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/A/Antibiotika-Resistenz-Strategie/BMG_DART_Bericht_10_RZ_03_web_neu.pdf

1. **Strengthening the One Health approach**: Recognition that the health of humans and animals when it comes to infectious diseases is closely linked will help identify future measures and activities.

2. **Recognising changes in resistance at an early stage**: Monitoring systems are being expanded in order to detect new pathogens and resistance at an early stage and to obtain representative data for the whole of Germany which will also be available for research.

3. **Retaining and improving therapy options**: The monitoring of antibiotic consumption is being further expanded. These data form, at the national level, the foundation for intervention measures. In addition, concepts for preparing and applying guidelines are being developed.

4. **Breaking chains of infection early and avoiding infections**: In both human and veterinary medicine, diagnostics are being improved and the implementation of hygiene measures are being supported. Livestock farming methods must be optimised.

5. **Raising awareness and strengthening skills**: Gaps in knowledge both in the general population and amongst doctors, veterinary surgeons, and other health professionals must be closed by the provision of target group specific information.

6. **Supporting research and development**: Research makes an important contribution to containing the increasing spread of antibiotic resistance. All the corresponding research areas in human and veterinary medicine are therefore being strengthened, from basic research through clinical research and research into public health matters to research in cooperation with the health, agricultural, and food sectors.

3 German stakeholder overview

The table below provides an overview of the key German stakeholders involved in tackling AMR. These include both the companies visited during the Global Expert Mission as well as other stakeholders. The visited stakeholders are involved in one or more of the 5 key strategies to curb AMR (see 2.2 above) and are represented in the table below:

Visited Organisations / Key Strategy	A	B	C	D	E
	Improved Prevention	Improved Stewardship	Improved Microbial Diagnostics	Novel Antimicrobials	Alternative Strategies
Authorities					
Federal Ministry of Education and Research					
Federal Ministry for Health (Berlin)					
Healthcare centers					
Charité University hospital (Berlin)					
University hospital Jena (Jena)					
University Hospital Frankfurt (Frankfurt)					
Academia & Research Centers					
Fraunhofer Institute Cell Therapy and					
Koch Institute (Berlin)					
Leibnitz Institute of Photonic Technology					
Pharma industry					
Adrenomed (Berlin)					
Aicuris (Wupertal)					
Diagnostics industry					
Thermofisher Scientific (Berlin)					
Blink (Jena)					
Curetis (Holzgerlingen)					
Bosch Healthcare (Waiblingen)					
Qiagen (Hilden)					
Funding organizations					
Welcome Trust (Berlin)					
Other					
Global AMR Hub (Berlin)					
Biocom (Berlin)					
Infectognostics (Jena)					

Table 2; Overview of visited organisations during the Global Expert Mission to Germany

3.1 German stakeholders involved in 'Improved Prevention'

3.1.1 German Federal Ministry of Health

As mentioned before, the German Federal Ministry of Health has launched its first DART plan to prevent AMR in 2008. Upon implementing the AMR strategy it became clear that Germany needed to work more collaboratively with its international counterparts and support capacity building if it was to address AMR. This has led to the appearance of an updated version of the DART. Since then the Ministry increasingly prioritise international collaboration as well as capacity building in the international context. The main focus therefore is on LMIC's.

In the discussions, the Ministry confirmed Germany's focus on the One Health approach, and their desire to avoid duplicating governance structures like the WHO's and UN's which in Germany's view are sufficiently in place already. The Ministry recognised that the UK has pushed the topic of AMR and that the UK has cooperated well with different international initiatives. Germany sees the UK as a key driver of the AMR global agenda, and in particular they (as did many other visited stakeholders as well) commended the work of Chief Medical Officer Dame Sally Davies and her value as a great spokesperson for the cause.

The Ministry of Health is responsible for policies relating to infection prevention and control and for approving the use of (novel) antibiotics. It was confirmed that the German decision making structures around implementation are rather conservative and slow to change and to adopt new funding models.

The Ministry only has a small budget to fund research that will help inform their policy. It funds the Robert Koch Institute (see below) but it will not fund other types of research.

3.1.2 The German Federal Ministry of Education and Research

The focus of the German Federal Ministry of Education and Research is on national measures and multilateral initiatives rather than on bilateral initiatives. They are open to dialogue with relevant stakeholders and working to find common interests, but not necessarily to set up formal cooperation structures. The existing and prominent French-German cooperation on AMR was more of a historic origin and for political reasons than a really science-driven partnership. France is often the 'partner of choice' for Germany on health issues but it seems that there is room to change this. There is appetite to work more closely with the UK and a possible collaboration with the UK on AMR is clearly valued.

The German Federal Ministry of Education and Research considers AMR as an important topic. They contribute financially to the DZIF (see below) and have been instrumental in setting up the Global R&D AMR R&D Hub (see also below).

The Ministry of Education and Research is the funding organization that the UK needs to engage with to fund collaborations between the UK and Germany. Currently most of the funding is invested within Germany. However the Ministry is taking part in international funding schemes, such as the Joint Programming Initiative in AMR (JPIAMR), Global Antibiotic Research and Development Partnership (GARDP), Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) and World Health Organisation (WHO). The total funding may be up to 500M Euro in 10 years from 2017. They would like to see the UK invest in GARDP.

3.1.3 The Robert Koch Institute

Since its founding in 1891, the Robert Koch Institute ('RKI') has been dedicated to the investigation and prevention of infectious diseases. Today, the institute is also responsible for nationwide health monitoring. Their collected data is included in the health reporting of the federal government. Around 1,080 people including 450 scientists are working at the RKI in five departments and more than 50 units. The RKI cooperates with many international partners like the ECDC and the WHO. RKI is the WHO Collaborating Centre for Emerging Infections and Biological Threats and also partner of

WHO's Global Outbreak Alert & Response Network, supporting affected countries world-wide to tackle outbreaks.[20]

RKI have been commissioned by the German Ministry of Health to explore ideas on possible global governance mechanisms. As the German equivalent to Public Health England (PHE) the RKI is the leading German institution for surveillance and capacity building. Germany doesn't seem to have a federal AMR environmental surveillance programme but there are some projects funded at a regional level. The RKI is collecting antibiotic resistance data from some 80 laboratories throughout Germany. In addition it is collecting the antibiotics consumption and antibiotics use data in primary care centers and at GP's.

The RKI has previously focused on Germany and tended to have an inward view equivalent to the US CDC. However they are looking to change this and clearly recognise the need for international collaborations.

In the domain of AMR the institute is involved in 4 types of international projects:

1. Capacity building and research in collaboration with the German Federal Ministry of Education and Research in Sub-Saharan Africa. Their experience of working in Africa proved that better microbiology analyses and data collection is needed and there is consequently a strong need for capacity building and standardisation within LMICs.
2. Surveillance and diagnosis-related activities in collaboration with the Fleming Fund in Nigeria
3. Various AMR-related activities and projects in Asia
4. Participation in different European projects (ARDIS and NOVA) in collaboration with the ECDC.

RKI are currently in the process of setting up an office for international cooperation within RKI. This office will provide the administrative link to help researchers at RKI work globally. The RKI are already working with UK researchers on the surveillance and African and Asian Resilience in Disaster Insurance Scheme (ARDIS) projects. They see an opportunity for more cooperation in the future, particularly given that Germany and the UK face many of the same problems in tackling AMR. Although there is a distinct difference between tropical medicine and global health, in Germany sometimes they are used interchangeably.

3.1.4 Charité Universitätsmedizin Berlin (Berlin)

Charité Universitätsmedizin Berlin (Charité) is one of the largest university hospitals in Europe. Charité represents a single medical faculty, which serves both Humboldt Universtität zu Berlin and Freie Universität Berlin. It extends over four campuses, and has close to 100 different departments and institutes, which make up a total of 17 different Charité Centers. Charité is one of the largest employers in Berlin, employing 14,576 staff (or 18,010 if including its subsidiaries), and with a total

[20] https://www.rki.de/EN/Home/homepage_node.html

annual turnover of €1.8 billion[21]. Concerning AMR the activities relate to every aspect of infection control, teaching and research. Since 1999 Charité is the national reference center for nosocomial ('hospital acquired') infections. Charité is involved in large German research projects such as the Surveillance AMR in Intensive Care Units (SARIC; 2001) and MRSA-related projects whereby it is informed on MRSA isolates from 600 German hospitals.

Charité are currently focussing a lot on education and stewardship as well as on infection control programmes, and are working with design companies to create tailored interventions for different target groups. They have been working on the 'Infozept' (information-prescription): a paper or digital prescription which provides advice and information for the patient, fulfilling their perceived need for a prescription, without using antibiotics. It has been well received by doctors (in 3 federal states so far) and they are looking to roll it out across Germany. Another initiative they have trialled is a 'tab' for doctors (a small handheld device) which they can use to track their own activity and receive direct feedback at the end of each day on how many antibiotic prescriptions they have written. This device however, was not very positively received by the doctors they trialled it with. Another issue raised was the difference in prescription behaviours by privately and publicly employed doctors – it was highlighted that doctors working in the private sector are more likely to prescribe antibiotics as patients are more likely to expect antibiotics in return for their payment.

Charité expressed their desire to stay in contact with UK stakeholders and to have more formal information exchanges, whether this was through multilateral channels (e.g. JPIAMR Virtual Research Institute), or bilateral exchange. They already have some more formal institutional cooperation in place with PHE and Imperial College, but there is scope for more. It might be useful to establish a formal mechanism to sharing information and best practices on AMR at a UK-Germany level.

3.1.5 The German Centre for Infection Research

The German Centre for Infection Research (Deutschen Zentrum für Infectionsforschung; DZIF) works to align translational research with unmet global medical needs caused by infectious diseases. The centre coordinates infection research in Germany to address national as well as global challenges with great societal impact as defined by the WHO health agenda[22]. DZIF's translational mission, therefore, includes the implementation gap as an integral part of its strategy. Also the development gap for antibiotics is steadily increasing. Research institutions have to rely on partners who are willing to share the economic risks with them and make their scientific contribution. This is exactly where DZIF comes in: in recent years, DZIF has become an important stakeholder in infection research and a reliable cooperation partner for the biotechnology and pharmaceutical industry in Germany.

[21] https://www.charite.de/en/
[22] https://www.who.int/about/vision/global_health_agenda/en/

Over 500 doctors and scientists from 35 establishments collaborate with DZIF, jointly developing new approaches to prevent, diagnose and treat infectious diseases. Their research areas include: novel antibiotics, emerging infections, tuberculosis, gastrointestinal infections, hepatitis, HIV, infections of the immunocompromised host, healthcare-associated and antibiotic-resistant bacterial infections and malaria.
They have their own funding already assigned to specific projects which are between 2-4 years, but they also have a small pot of funding named the "Flex-Fund" for new projects. This was highlighted as a potential opportunity and worth exploring the potential to establish a joint UK-German partnership with both jointly funding collaborative projects from their respective budgets (e.g. the Flex-Fund from DZIF and an equivalent fund from the UK).

This synergistic alliance of universities, hospitals and research institutions has resulted in a national infrastructure aiming to effectively translate research results from bench to bedside, and vice versa: applying insights from clinical practice to research.

Since its inception, DZIF has been strengthening collaborations with partner institutions in Africa to investigate diseases like malaria, tuberculosis and HIV. DZIF is one of nine founding organisations of CARA (Conscience of AMR Accountability): an international alliance that aims to ensure that effective antibiotics will also be globally available in future. The main office of DZIF is located in Braunschweig[23].

Meeting with a DZIF representative in Frankfurt

3.2 German stakeholders involved in 'Improved stewardship'

Charité and DZIF are the key stakeholders in Germany when it comes to improving the stewardship of antimicrobials. [*additional text to follow*?].

[23] https://www.dzif.de/en

3.3 German stakeholders involved in 'Improved diagnostics'

3.3.1 Fraunhofer Institutes (Potsdam)

The Fraunhofer Society for the Advancement of Applied Research was created in 1949. Fraunhofer is Europe's largest application-oriented research organisation. Its research activities are conducted by 72 institutes and research units at locations throughout Germany. The Fraunhofer-Gesellschaft employs more than 26,600 staff who work with an annual research budget of 2.6 billion euros. Of this sum, 2.2 billion euros is generated through contract research. Around 70 percent of the Fraunhofer-Gesellschaft's contract research revenue is derived from contracts with industry and from publicly financed research projects[24].

The Fraunhofer Institute is considered to be an international leader in applied science. The Fraunhofer doesn't act to market or sell any of its products, but instead depends on (clinical) development, commercialisation and marketing partners. For several reasons it could be of interest for the UK to further unlock the potential of Fraunhofer and make the institute more known in the UK.

The Fraunhofer Institute for Cell Therapy and Immunology IZI investigates and develops solutions to specific problems at the interface of medicine, life sciences and engineering. One of the institute's main tasks is to conduct contract research for companies, hospitals, diagnostic laboratories and research institutes operating in the field of biotechnology, pharma-ceuticals and medical engineering.[25] The Bioanalytics and Bioprocesses Branch in Potsdam-Golm (IZI-BB) as affiliated with the Fraunhofer Institute for Cell Therapy and Immunology on July 1, 2014. The site was initially founded in 2005 as a branch of the Fraunhofer Institute for Biomedical Engineering Fraunhofer-Institut für Biomedizinische Technik (IBMT) and has since worked on technological solutions for biomedicine and diagnostics as well as for biotechnology and bioproduction.

AMR is an important theme at the IZI-BB. One of the focal areas is rapid testing systems / Point-of-care-testing and AMR. Thanks to the production system they have on site, they are able to take an idea to a packaged product. The institute is teaming up with Charité and the RKI. In Germany the IZI-BB is a preferred partner for AMR diagnostics collaborations.

The UK Catapult Centres were created in 2011 based on the model of the German Fraunhofer Institutes. The Fraunhofer Institutes do not cover necessarily what the UK Catapults cover. As mentioned before it might be worth exploring the possibility for the Catapults and Fraunhofer Institutes to interact in complementary areas and support UK/German companies.

[24] https://www.fraunhofer.de/en.html
[25] https://www.izi.fraunhofer.de/en.html

Fraunhofer Institute: paved road to the institute and group picture

Fraunhofer and then: Pizza in Potsdam with our hosts

3.3.2 InfectoGnostics Campus (Jena)

The InfectoGnostics research campus is a public-private partnership (with funding from the German Ministry of Education and Research) whose aim is to bring industry and academia together and to bridge the value-chain gap. The campus is developing new methods in infection diagnostics. In a triad of technology, application and production, more than 30 partners from science, medicine and industry are developing marketable solutions for rapid and cost-effective on-site analysis (point-of-care testing) of infections – such as pneumonia and tuberculosis in human medicine, animal diseases, and pathogen detection in food.

InfectoGnostics is strongly rooted in the research landscape of Thuringia and regionally and nationally connected with 10 other research institutions and is a member of 4 national and European organisations[26].

[26] https://www.infectognostics.de/en/

As mentioned, the InfectoGnostic programme has a unique Public Private Partnership model that links hospitals, researchers and industry. The research campus is interested in international collaborations and the possibility to include new partners in its programme. The Center for Excellence in Sepsis is based in Jena Hospital and it plays a significant role in the clinical validation of technology and access to samples. The hospital also has a pathogen biobank. There might be substantial interest from UK academics and companies to collaborate in order to gain access to the large amounts of patient samples as well as to big data and to bring in their expertise and services.

The InfectoGnostics campus are most interested in collaborations on an individual project basis, where sharing expertise makes sense. Currently, the barriers to international collaboration include the requirement for sufficient co-funding and differences in regulatory pathways.

The ultimate goal of InfectoGnostics is to be a European Centre for Infection Research. To this end they are constantly seeking new partnerships and also would like to engage in more formal international relationships. The UK NHS and MRC are seen as the UK strengths.

Although the region has some pharma companies, the strength of the InfectoGnostics Campus and surrounding areas is instrumentation for diagnostics around optics and photonics.

The UK delegation visiting InfectoGnostics Campus (Jena)

3.3.3 BLINK DX (Jena)

BLINK DX is a partner of the InfectoGnostics Research Campus. Blink was founded in 2015 by Eugen Ermantraut, Torsten Schulz and Thomas Ellinger. Many members of the BLINK's team have previously developed, built and deployed some of the most advanced point-of-care products currently available. BLINK is taking the next step towards creating a holistic product platform for near patient use. Their assay development model is designed to enable the in vitro diagnostics community to quickly develop and deploy point-of-care tests on a shared development and product

platform. Blink is building a customised diagnostic toolset that enables developers, both large and small, to create a diverse and meaningful menu of tests to meet the many and varied needs of healthcare professionals, researchers and the patients[27]. The platform provides ample opportunities to UK academics and SME's for (co-)development of novel diagnostic tests.

Local food in Jena the day before visiting InfectoGnostics

3.3.4 Qiagen (Hilden)

Qiagen is a provider of sample and assay technologies for molecular diagnostics, applied testing, academic and pharmaceutical research. Consolidated under the Dutch holding QIAGEN N.V., the company operates more than 35 offices in over 25 countries. QIAGEN is known to more than 500,000 customers around the world for its innovations[28].
Qiagen define themselves as the world's biggest bio-informatic company. The company have a strong interest in the microbiome and could well be linked to the UK Microbiome SIG (special interest group).

According to Qiagen the future of AMR will focus on personalised medicine. It is agreed that that the concept of companion diagnostics might be useful in curbing global AMR.

[Additional discussions, opportunities, strengths, challenges to follow?]

3.3.5 Curetis (Holzgerlingen)

Curetis is a molecular microbiology diagnostics company addressing the challenge of detecting infectious diseases and identifying antibiotic resistances in hospitalised patients. Their Unyvero A50 System is a molecular diagnostics platform used for diagnosis of severe infectious diseases. The system uses multiplex PCR technology to detect a wide variety of microorganisms, antibiotic resistance markers, or toxins from sample-to-answer within 4-5 hours. So far the market acceptance of the Unyvero System has been limited. According Curetis health economic studies have demonstrated that the technology is viable. The reason that it has not been picked up may be because of the slow nature of behavioural change. Curetis claims to have placements in the UK and partners are keen but they find that the reimbursement issue continues to be problematic. In

[27] https://www.blink-dx.com/
[28] https://www.qiagen.com/nl/

addition wide adoption of AMR and infectious diseases point-of-care diagnostic tools require complex implementation packages which slow down market implementation.

3.3.6 Bosch Healthcare Solutions (Waiblingen)

Bosch Healthcare Solutions is a spin off initiative of Bosch. Its products and solutions build on the core competencies of the Bosch Group. These include sensor and microsystem technology, miniaturisation, and smart networking.

With Vivalytic, Bosch Healthcare is presenting a universal platform for molecular diagnostics which analyses a wide variety of sample materials in an automated way. The Vivalytic platform combines different analysis methods in one device and is open to providers for further tests. Bosch Healthcare has partnered with UK-based Randox and is looking for more distributors. Bosch Healthcare would also be interested in gaining access to clinical networks and diagnostics-related expertise in the UK.

The existing partnership with Randox has developed through delivering a molecular diagnostics solution for a number of conditions including respiratory infectious diseases and sexually transmittable diseases. Bosch Healthcare provides the diagnostic system expertise and Randox provides the molecular diagnostic assay expertise. In future, there could be opportunities for other UK/German companies to develop similar partnerships.

The formal Bosch Healthcare Systems group picture in Waiblingen

3.3.7 ThermoFisher Scientific BRAHMS (Henningsdorf)

ThermoFisher Scientific BRAHMS research focuses on identifying novel biomarkers to develop and manufacture novel diagnostic tools to improve early diagnosis and treatment of life threatening

diseases. These include immunodiagnostic tests for prenatal screening, cardiovascular, pulmonary, and cancer disorders as well as sepsis. They are part of the InfectControl 2020 consortium which brings industry and researchers together to develop and commercialise new strategies for the early diagnostic, control and fight infectious diseases. InfectControl 2020[29] is a consortium of representatives from enterprises and academia that jointly aims at developing solutions regarding the problems related to AMR on a national and global level. Andrenomed and ThermoFisher are part of the industrial partners, Charité, University Clinic Jena and RKI are part of the research partners.

3.4 German stakeholders involved in 'Novel Antimicrobials'

3.4.1 AiCuris (Wuppertal)

AiCuris (from 'Anti-infective Cures') is a pharmaceutical company focused on the discovery, research and development of novel antiviral and antibacterial agents for the treatment of severe and potentially life-threatening infectious diseases. Founded in 2006 from Bayer's virology and bacteriology research divisions, AiCuris today has an innovative pipeline of novel anti-infectives. Bayer still owns part of the company and therefore AiCuris are considered as a large enterprise under the EC definition.

AiCuris is constantly evaluating strategic partnerships and collaboration opportunities with biotech or pharmaceutical companies.[30] The company is interested in use and access to big data including infection intelligence platforms, artificial intelligence and gene sequencing data.
The focus of AiCuris is on high-throughput screening from natural products as well as new approaches. The company have received funding for projects from the EU and the German Ministry of Education.
For their drug discovery and development activities the company collaborates with the US and Europe, including universities and service providers in the UK. They noted that their experience of working internationally had been complicated at times and any new bilateral collaboration needs to be simple with limited restrictions. They felt that collaborating with partners for the sake of accessing funding is wrong.

3.5 German stakeholders involved 'Alternative antimicrobial strategies'

The Global Expert Mission 'AMR Germany' hasn't really seen much of this topic. The well-developed attention in Germany to alternative antimicrobial strategies like natural products, probiotics and microbiotics may provide interesting collaboration opportunities in the UK.

[29] https://www.infectcontrol.de/de/english.html
[30] http://www.aicuris.com/1/Home.htm

3.5.1 Adrenomed (Hennigsdorf)

Adrenomed AG is a privately-financed, clinical-stage biopharmaceutical company with a clear mission: to rescue vascular integrity in order to save the lives of critically ill patients with limited treatment options. Their treatment approach combines the therapeutic antibody with a specific diagnostic, which uses Adrenomedullin as the biomarker to identify patients. The most important target indications are sepsis and septic shock as well as acute heart failure. Also Adrenomed is a member of the InfectControl 2020 consortium.

3.6 Other relevant German stakeholders

3.6.1 The Global AMR R&D Hub (Berlin)

In 2017, the G20 heads of state and government took the decision to intensify global collaboration in the fight against AMR. The German Federal Ministry of Education and Research then proposed plans for a Global AMR Research and Development Hub[31] – or Global AMR R&D Hub for short.
The Hub was launched on 22 May 2018 coinciding with the World Health Assembly in Geneva. The Hub aims to improve further the coordination of international efforts and initiatives to tackle AMR while further increasing investments into R&D for AMR. Since then the Wellcome Trust and the Bill & Melinda Gates Foundations have joined the Hub. The WHO, FAO, World Organisation for Animal Health (OIE) and Organisation for Economic Co-operation and Development (OECD) are observing members. [is the UK government a member?]

The secretariat of the Global AMR R&D Hub is based in Berlin, at the German Center for Infection Research (DZIF). By the end of 2019 the Hub is expected to launch the first version of its global 'Dynamic Dashboard' which builds on existing mapping carried out by JPIAMR and others. The Dynamic Dashboard will provide easy to read, up to date, global information and incentives on AMR-related R&D on diagnostics, therapeutics, vaccines and alternative therapies like phage therapy. Resistance data is not included. The data on the dashboard will be used to formulate national recommendations and suggestions for incentive schemes.

The newly established expert advisory group of the hub started earlier in May 2019 and the names of its members will be published shortly.

The Global AMR Hub has been met with some sceptics; there is some concern as to the added value of the Hub, particularly when existing UN/WHO structures already provide governance at an international level. In that regard, the existence of the Hub contradicts somewhat Germany's position that there is no need for further global governance structures since the leadership required is provided already by the WHO and the tripartite. Meanwhile the investment in the Global R&D Hub

[31] https://www.gesundheitsforschung-bmbf.de/en/GlobalAMRHub.php

shows commitment from the German government to tackle AMR. The outcomes of the Hub and how it hopes to differentiate itself from existing structures still needs clarity.

3.6.2 The German office of the Wellcome Trust (Berlin)

The Wellcome Trust is a biomedical research charity based in London, United Kingdom. It was established in 1936 with legacies from the pharmaceutical magnate Sir Henry Wellcome to fund research to improve human and animal health. As an international organisation they do not want to be seen as a UK only or UK focus organisation. Since early 2019, the Wellcome Trust has its first foreign office in Berlin. The team is primarily focused on policy and does not have the ambition to replicate the London Headquarters of the Wellcome Trust. Consequently, all funding activities will stay in the UK. In future the Wellcome Trust Berlin will act as a vehicle to engage with other European countries.

AMR and epidemic preparedness are the two priority areas for the Berlin office: the aim is merely to strengthen and deepen existing contacts with CARB-X and the Global R&D hub and to gain inside knowledge and build contacts within the German government. It makes sense for Innovate UK to work with the Wellcome Trust on AMR. They are in a good position to open doors and to make introductions to relevant German stakeholders especially at government level. The Berlin office has the will to work with Innovate UK and to join forces as long as the activities fit their remit.

3.6.3 Biocom

Biocom is a Life Sciences B2B communications company working for various target groups in business, politics, science and the general public. Biocom focuses on high-tech areas of the life sciences: biotechnology, bioeconomy and medical technology. Biocom is the organiser of an annual 'AMR Conference' (in 2020 on 12-13 March). This event may be a good opportunity to meet with AMR German stakeholders. There may be the potential opportunity to work with Biocom to raise the UK profile by setting up a UK side event to promote UK activities in the AMR area.

The Evotec-Bridges Programme[32] to accelerate research and early development in therapeutic areas of unmet medical need including infectious diseases were mentioned. Evotec is a major player on therapeutics on Antibiotic Research, they took over from Sanofi.

3.6.4 Boehringer Ingelheim Venture Fund

[text resulting from the skype session..]

[32] https://www.evotec.com/en/innovate/bridges

3.6.5 Additional German initiatives that may be relevant to the field of AMR

[I leave it up to you if you want to leave out 3.6.5.1 and 3.6.6]

3.6.5.1 BIO Germany

As the sector association of the biotechnology industry, BIO Germany has set itself the objective of supporting and promoting the development of an innovative economic sector based on modern biosciences. The Berlin-based association currently has over 330 members including companies in the AMR space: AiCuris, Vakzine Project Management, Hyglos, Curetis, Artes, Progen and Noscendo[33].

3.6.6 German bioclusters involved in AMR

The biotechnology regions in Germany have provided an effective impetus for commercialisation. Approximately 25 bioregions with just under 600 biotech companies have been established since the late 1990s, which is quite a respectable achievement from an international perspective.[34] Some 10 bioregions are involved in diagnostic activities (which is broader than only microbial / infection diagnostics). The following regions are involved in AMR:

1. BioRegioN for its vaccine research (www.bioregion.de)
2. BioRiver for its activities in infectology (www.bioriver.de)
3. IGZ-Innovation & Entrepreneur Center Bavaria for its activities in infection biology and microbiology (www.igz.wuerzburg.de)
4. BMD Life Sciences Agency for its activities in vaccination research (www.bmdlifesciences.de)
5. Infectognostics for its activities in infection diagnostics, companion diagnostics (www.infectognostics.de).

Figure 1: Overview German Bioclusters (Source: German Trade & Invest)

[33] https://www.biodeutschland.org/en/home.html

[34] https://d-nb.info/971374856/34

4 Overall observations

Following this Global Expert Mission to AMR, and the many discussions with German stakeholders, a number of overall observations can be made:

It is evident that Germany and the UK have the same sense of urgency and convincing solution-oriented attitude when it comes to the need to curb AMR. The German organisations visited during the mission show a clear appetite to collaborate with their UK counterparts and other UK organisations. It is aid by the fact that many German institutions and stakeholders recognise the UK as a global leader in pushing the global AMR agenda.

Whereas the UK has a global view on tackling AMR, it seems that Germany at least so far is more inward oriented. For historic reasons the UK has AMR-related networks and laboratories in many different countries including several LMIC's. Germany has started to realise that AMR, due to its very nature, cannot only be curbed within and by Germany itself. So far, the country has limited experience, expertise and access to AMR-related capacity in the LMIC's. However the country is in the process of expanding its AMR-related capacity building activities in the LMIC's. Therefore the UK is well positioned to act as a natural partner for Germany in this instance.

Both the UK and Germany are very good at basic and applied research. In both countries translational research remains a challenge. In Germany, it is perceived that there is a lack of entrepreneurs and a real lack of funding and investments for AMR-related start-up's. In this respect the UK is perceived as a better environment.

It must be concluded that the national debate and the national conversation on AMR work differently in Germany when compared to the UK. The overall approach of the national UK 20-year strategy on AMR and the German DART strategy also show a different approach to curb AMR. It should be acknowledged that Germany, in contrast to the UK, lacks an overall, national approach. In fact the different federal states have their own and different approaches and responsibilities when it comes to curbing AMR. In daily practice it is difficult for a region to know the stakeholders of other, even neighbouring regions and what AMR-related initiatives have been taken. This complicates the development of an overall German AMR strategy and approach. In Germany there is no national central AMR contact point.

The funding landscape in Germany exists at both a national and regional level. Wealthier regions have an advantage over less wealthy regions. Federal states compete with each other for national funding and most likely also when attracting foreign companies and investments. Germany could benefit from a network model like the KTN that can join all the regional networks.

The Global AMR R&D Hub in Berlin, seems to be surrounded by a number of ambiguities and would do well by providing further clarity on its vision, mission and strategic agenda. The function and added value of the hub are not fully evident yet and the question may arise if the Hub is merely a political prestige project rather than an effective global steering instrument. Also there might be some overlap between JPIAMR and the Global R&D Hub. The anticipated Dynamic Dashboard which will be launched later this year is eagerly awaited.

When considering the efforts to combat AMR, overall the UK tends to be rather pragmatic, more flexible and transition across different scientific disciplines. Tackling AMR does require a holistic approach that needs to consider the entire 'One Health' system. Cross-overs and entirely new scientific domains like the social sciences need to be embraced rather than isolated. The German scientific and healthcare worlds tend to adhere to a more traditional, segregated, less flexible monodisciplinary approach.

It must be mentioned that German hospitals can't escape the heavy bureaucracy which makes implementing swift antimicrobial stewardship measures much harder than in the UK. Also the private medical doctors in Germany have and stick to a substantial autonomy when it comes to prescribing antibiotics.

Reimbursement for novel diagnostics and antimicrobials is clearly an issue in Germany. It is necessary to convince individual hospitals and GPs to use the novel products. These may hamper an easy introduction of UK products on the German market. The same applies to the regulatory and Intellectual Property aspects of UK antimicrobials, diagnostics and related services to be introduced in Germany.

The possible synergy between diagnostics and antimicrobials needs to be worked out further. Pharma and diagnostic companies do not move in the same sphere and there might be a need to bring them together within the concept of 'companion diagnostics'.

When considering building new collaborations between the UK and Germany one has to realise that novel funding mechanisms may need to be created. Although there are some European initiatives where both countries fit in e.g. Horizon 2020, the Innovative Medicine Initiative (IMI), EUREKA, Small Business Research Initiative (SBRI) grants, European Antimicrobial Resistance Surveillance Network (EARSNET) and Combatting bacterial resistance in Europe (COMBACTE). However, there are no existing models dedicated to bilateral UK – German collaboration.

As stated before there seems to be an substantive fit between the UK and Germany in tackling AMR; there is an open and constructive attitude towards collaborating and there are good existing interactions between the two countries. A potential bottleneck may be Brexit. The anticipated impact of Brexit needs to be considered at two levels:

1. Impact of Brexit on investment decisions by foreign companies in the UK
2. Impact of Brexit on collaboration and communication between foreign and UK organisations.

4.1 Observed German strengths and weaknesses in the AMR space

Overall the following German strengths and weaknesses were observed:

	Strengths	Weaknesses
AMR in general	• Political willingness to tackle AMR • Host Global R&D Hub (Berlin) • Much funding for research • In depth, monodisciplinary research • Campus concepts & incubators	• Lack of translational research • Lack of a national AMR approach • Regional competition rather than collaboration • Lack of expertise and experience in multidisciplinary collaboration in AMR • Inward looking and with a limited international focus, however growing • Regional rather than a national approach on AMR • No central AMR contact point/coordination centre, no network of networks • No national Knowledge Transfer Network
Prevention	• RKI / Charité / DZIF strong bodies • Good surveillance system	• Lack of infection-related medical doctors at German hospitals • Bureaucracy in German hospitals
Stewardship	• Programs and protocols available in hospitals	• Programs not always followed up
Diagnostics	• Strong diagnostics sector • Strong engineering and instrument-based approach • Solid manufacturing infrastructure for instruments • InfectoGnostics as a strong body	• Technology over-push • Lack of start-up's & translational research • Clinical development hard • Hospital implementation difficult
Antimicrobials	• Focus on natural products • Key players Evotec, Aicuris	• Lack of funding for start-up's • Lack of entrepreneurs
Alternatives	• Focus on microbiotics to treat AMR • Focus on probiotics, antibodies and phage lysins • Focus on natural products	• [text?]

Table 3; observed strengths and weaknesses related to AMR in Germany

German strength: electronics and engineering at Fraunhofer in Potsdam

4.2 Observed UK strengths and weaknesses in the AMR space

Overall the following strengths and weaknesses were brought in by the mission delegates:

	Strengths	Weaknesses
AMR in general	• Outward looking and not afraid to assume a global AMR leadership role (AMR Review, AMR Champion Dame Sally Davies) • UK 5-year AMR Strategy 2018-2023 • UK 20-year vision for AMR to contain and control AMR • Easy access to funding (Wellcome, Fleming) • Well-developed data infrastructure (Oxford, Edinburgh, Sanger Data Centers, Catapult centers) • Able to respond quickly to global outbreaks (Ebola, Zika) • National debate on AMR with a dedicated UKRI Council AMR Initiative, AMR Centre • Well-developed national AMR networks and KTN as a national Technology Transfer Network • Large range of AMR-related courses, education and workshops • Multidisciplinary approaches in AMR well developed	• Brexit-related uncertainties • Lack of translational research • Limited collaborations with foreign (non-UK) companies
Prevention	•	•
Stewardship	• Interdisciplinary approaches • Social sciences well developed	• Lack of control on doctors • Need for more education
Diagnostics	• Strong diagnostics industrial sector • Long tradition in developing assays • Excellent infrastructure for research and innovation • Well-developed end user (hospital) / industry relationships • Well-developed biobanking & bio-informatics • Lead in regulatory for EU • Strong notified bodies • Long term collaboration with LMIC's • Expertise (e.g. in screening)	• Big diagnostics companies sold • Manufacturing taken back • Instrumentation less developed • Limited traction in adoption and spreading of new tests • Too many pilot projects • Lack of health economics studies • Lack of market pull incentives • Lack of joint initiatives for companion diagnostics
Antimicrobials	• Organic chemistry well developed • AMR Centre Alderley Park • Contract research & clinical trials well developed • Golden triangle: London/Oxford/Cambridge	• No link with the diagnostics sector • Lack of follow up funding • Limited big Pharma involvement in AMR • Lack of market pull incentives
Alternatives	• Early adaptor SME's • Microbiome-related research and SME's (Procarta)	• [text?]

Table 4; observed strengths and weaknesses related to AMR in Germany

5 Conclusions and strategic recommendations

5.1 Overall conclusions

Following the Global Expert Mission AMR Germany, the following may be concluded:

5.1.1 Collaboration potential: the UK to benefit from German strengths

Ad Improved Diagnostics: The UK may well benefit from the German well developed engineering expertise and manufacturing infrastructure. In addition, German Diagnostics companies like BLINK and Bosch Healthcare Solutions have diagnostics platforms which may offer interesting co-development opportunities for UK Academia and SME's. UK co-development and sales organisations like Randox can be instrumental in the development and commercialisation of German diagnostics tests in the UK.
Ad Novel Antimicrobials: the UK may offer contract research and clinical development services to companies involved in antimicrobial R&D such as the German AiCuris.
Ad Alternative Strategies: the well-developed attention in Germany to alternative antimicrobial strategies like natural products, probiotics and microbiotics may provide interesting collaboration opportunities in the UK.

5.1.2 Collaboration potential: the UK to compensate for German weaknesses

It goes without saying that the UK does have a lot to offer to Germany when it comes to tackling AMR:
Ad Improved Prevention: Germany may well benefit from the globally leading role the UK has assumed when it comes to curbing AMR. The UK may support Germany in its international capacity building initiatives. Also Germany may benefit from the available data analyses expertise and infrastructure in the UK. Also the UK could be helpful in implementing a more flexible, multidisciplinary approach to tackling AMR in Germany including the increased use of social sciences.
Ad Improved Stewardship: the UK may bring in its well-developed training and educational experience when it comes to raising awareness amongst doctors in German hospitals.
Ad Improved Diagnostics: the UK may bring in its end-user hospital/industry relationship and contract research and clinical development infrastructure to German diagnostics companies. Germany also could benefit from UKs greater translational expertise.

5.1.3 Collaboration opportunities

As mentioned above the Global Expert Mission to Germany has revealed quite some collaboration opportunities which may serve to strengthen the AMR-related innovation potential in both countries. These include in/out licensing, co-development, commercialisation, funding, research collaboration and education and training opportunities.
In order to initiate and develop such collaborations, different approaches may be used varying from short term initiatives such as organising follow up missions, round tables/workshops, networking events, exchanging data and longer term setting up joint UK-German funding calls and for UK-German research collaboration programs.

5.2 Recommended strategic objectives

All in all, the following 13 strategic objectives are identified:

Key Strategies:		Strategic objectives:	German parties include:
Improved Prevention	**1**	Reinforce German capacity building in LMIC	RKI, Charite
	2	Capitalize on UK (big) data expertise and infrastructure	RKI, Charite, Infectognostics, DZIF
Improved Stewardship	**3**	Support German implementation stewardship programs	German Hospitals
	4	Support creating awareness on AMR in German hospitals	German Hospitals
Improved Diagnostics	**5**	Co-develop / help testing German diagnostic tools	Bosch HS, Blink, Qiagen, Fraunhofer
	6	Help commercialising German diagnostics in the UK	Bosch HS, Blink, Qiagen, Curetis
	7	Explore opportunities for companion diagnostics	Tbd
Novel Antimicrobials	**8**	Capitalize on UK contract (clinical) development	AiCuris
Alternative Strategies	**9**	Explore opportunities for UK German collaboration	Fraunhofer, Adrenomed
General	**10**	Stimulate joint research on AMR	Fraunhofer
	11	Support development coherent German AMR strategy	Ministry of Health
	12	Support setting up a national AMR Hub (compare China)	Ministry of Health
	13	Improve UK German familiarity (innovation, business)	All German stakeholders in AMR

5.2.1 Reinforce German capacity building in LMIC (1)

5.2.1.1 Why

AMR is a global challenge that manifests itself explicitly in the LMICs. In these countries there is clearly a lot to gain. Although Germany is active in some of the LMICs, there seems to be a substantial need for additional capacity building and a more effective implementation of infection prevention, antibiotic stewardship and appropriate diagnosis of infectious diseases.

5.2.1.2 How

The UK is well positioned to reinforce the German AMR-related initiatives in the LMICs by bringing in their extensive global networks and their proven experience in setting up and sustaining diagnostic centres and reference laboratories in LMICs.

5.2.1.3 What

The UK may develop an overall strategy and/or more focused action plans on how German professionals may set up novel centres and laboratories and/or make existing ones more effective in a sustainable manner.

5.2.1.4 Next step

The next step would be to raise this idea in a round table session with RKI and to discuss the German interest, funding possibilities and approach.

5.2.2 Capitalize on UK big data expertise and infrastructure (2)

5.2.2.1 Why

The global curbing of AMR demands for an increasing use of big data expertise and infrastructure. Artificial intelligence, machine learning and also Internet-of-Diagnostic-Things and blockchain technology increasingly must support the key strategies to corner AMR: a better prevention of infectious diseases, controlled use of antimicrobials, novel diagnostics, antimicrobials and alternative strategies. The GEM has revealed that Germany is generating and collecting massive amounts of AMR-related data. Meanwhile we got the impression that the country lacks the expertise and infrastructure to effectively analyse and use these data.

5.2.2.2 How

The UK can boast of some established data centres like the University of Oxford Big Data Centre. Edinburgh has the aim to become the data capital of Europe. The available expertise and infrastructure can be made available to institutes like RKI, Charité, InfectoGnostics and DZIF.

5.2.2.3 What

Bilateral collaborations can be set up whereby the mentioned German organisations can bring in their data and UK organisations can bring in their data expertise and infrastructure.

5.2.2.4 Next step

The next step would be to set up a dedicated UK mission to visit mentioned German organizations to identify concrete German projects and programs where the UK can bring in their data expertise and infrastructure. In addition it should be worked out how this can be funded and how longer term strategic collaborations may be worked out.

5.2.3 Support German implementation stewardship programs (3)

5.2.3.1 Why

Effective antibiotic/antimicrobial stewardship is the cornerstone of an effective AMR strategy. The GEM gave the impression that stewardship does not yet reach full maturity in Germany due to the lack of national guidelines, regional differences and the rather traditional and autonomous German medical professionals and monodisciplinary approach within the German healthcare system. The UK is clearly a few steps further down the road.

5.2.3.2 How

The UK may be able to support Germany in setting up a national approach and/or strategy to implement an effective, widely supported stewardship program. In addition, the UK may be instrumental in implementing this strategy in a sustainable manner.

5.2.3.3 What

What would be needed is a strategic plan as well as an action plan to develop and implement such UK support.

5.2.3.4 Next step

The next step would be to discuss this possibility, explore the German interest and work out the required funding with delegates from the Ministry of Health, RKI, Charité and other large German hospitals in one or more round table sessions.

5.2.4 Support creating awareness on AMR in German hospitals (4)

5.2.4.1 Why

Awareness on AMR, in particular in hospitals and other health centres, is of great importance or even a prerequisite for implementing an effective AMR strategy. From the GEM we got the impression that in German health centres AMR does not attract the attention which it clearly deserves. In addition, there is a clear lack of infection prevention specialists and medical microbiologists. These professionals normally play an important role in creating the awareness.

5.2.4.2 How

Starting from their own experience the UK may bring in their experience in AMR awareness campaigns and their multidisciplinary approach when it comes to creating awareness.

5.2.4.3 What

What would be needed is a strategic plan as well as an action plan to develop and implement such UK support.

5.2.4.4 Next step

The next step would be to discuss this possibility, explore the German interest and work out the required funding with delegates from the Ministry of Health, RKI, Charité and other large German hospitals in one or more round table sessions.

5.2.5 Co-develop / help testing German diagnostic tools (5)

5.2.5.1 Why

Diagnostic tools are of great importance when it comes to curbing AMR. This applies to both the identification as well the sensitivity analyses which in fact guide the involved GP, doctor or veterinarian to prescribe the proper antimicrobial (or not to prescribe..).

5.2.5.2 How

Germany is very well positioned when it comes to the engineering and manufacturing of diagnostics hardware, electronics and (co-development) diagnostics platforms. Meanwhile the UK has a lot to offer in the complementary domain of novel, cutting edge screening and test systems. So there may be a clear synergy between the two countries related to developing novel microbial diagnostic tools.

5.2.5.3 What

The best way to explore the possible collaboration between German 'hardware providers' and UK 'screening and test systems providers' is to give both sides a current overview of what is available and what is offered. In addition, matchmaking meetings can be organised to bring both sides together in an effective way.

5.2.5.4 Next step

The next step would be to invite German companies like Bosch Healthcare Systems, Qiagen, Blink and Curetis to visit research centres, SME's and larger diagnostics companies in the UK.

5.2.6 Help commercialising German diagnostics in the UK (6)

5.2.6.1 Why

As stated above microbial diagnostics play an important role in preventing and curbing AMR. Quite some novel diagnostic tests and diagnostics platforms are being developed in Germany. These should get all possibilities for testing, validation and implementation.

5.2.6.2 How

Many diagnostics companies, especially in Germany, are facing difficulties in testing, validating and implementing novel diagnostics systems in their own country. This has to deal with the rather traditional, autonomous and rigid German healthcare system and the lack of appropriate funding by insurance companies. In the UK the interface between diagnostics companies and health institutions and diagnostics laboratories is much better developed. This could be of help to German diagnostics companies.

5.2.6.3 What

The best way would be to provide access for German diagnostics companies to UK healthcare institutions and to facilitate the German companies in testing, validating and implementing their novel test systems. It must be realised that, if successful, this may be at the cost of the UK diagnostics companies.

5.2.6.4 Next step

The next step would be to invite German companies like Bosch Healthcare Systems, Qiagen, Blink and Curetis to visit UK academic hospitals, healthcare centres and diagnostic laboratories.

5.2.7 Explore opportunities for companion diagnostics (7)

5.2.7.1 Why

A companion diagnostic is a medical device, often an in vitro device, which provides information that is essential for the safe and effective use of a corresponding drug or biological product. The test helps a health care professional determine whether a particular therapeutic product's benefits to patients will outweigh any potential serious side effects or risks. Companion diagnostics can:

- identify patients who are most likely to benefit from a particular therapeutic product;
- identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or
- monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness.

If the diagnostic test is inaccurate, then the treatment decision based on that test may not be optimal[35]. The concept of companion diagnostics to prevent and curb AMR is relatively new but may provide advantages when it comes to accuracy of testing, healthcare costs involved and to preventing AMR.

5.2.7.2 How

Before deciding whether or not to invest in research, development and commercialisation of companion diagnostics the two countries should investigate the potential and added value of the concept.

5.2.7.3 What

The best way would be to investigate the technical, economic and social ('acceptance by doctors') feasibility of the concept. In fact German as well as UK diagnostics and antimicrobials companies need to be involved and could possibly contribute to the costs involved.

5.2.7.4 Next step

The next step would be that the UK and Germany jointly work out the set-up of the feasibility study as well as the deliverables, needed capacity, time schedule, costs involved and arrange the required funding. The upcoming AMR Insights symposium 'Emerging Antimicrobials and Diagnostics in AMR 2019' on 19-20 November in Amsterdam provides a dedicated 'Buzz session' on companion diagnostics led by Prof. Till Bachmann. This session may be used as the starting point for the study.

5.2.8 Capitalize on UK contract (clinical) development (8)

5.2.8.1 Why

The effective curbing of AMR demands for a continuous inflow of novel, effective antibiotics and other antimicrobial products. The research and development of such products is challenging for several reasons. One of these reasons is the demand for a positive (clinical) development climate

[35] https://www.fda.gov/medical-devices/vitro-diagnostics/companion-diagnostics

created by professional (clinical) contract research organisations, cooperating hospitals and analyses laboratories.

5.2.8.2 How

The GEM gave us the impression that the German (clinical) development climate has its limitations. In contrast, the UK climate seems to offer a much more attractive climate. This has led to the idea to facilitate German antimicrobials companies like AiCuris by offering an attractive (clinical) development environment in the UK.

5.2.8.3 What

In fact the mentioned German companies should be introduced to UK (contract) research organisations, hospitals and analyses laboratories in an effective way.

5.2.8.4 Next step

A next step could be to enrol the involved German and UK in a novel UK-German call for antimicrobials research.

5.2.9 Explore opportunities UK German collaboration on alternative antimicrobials (9)

5.2.9.1 Why

Alternative antimicrobial strategies like phage therapy, natural compounds, DNA-based CRISPR-Cas technology are of vital importance and deserve our attention when it comes to the development and commercialisation of these products.

5.2.9.2 How

Germany has quite some interesting organisations involved in the R&D of alternative antimicrobials, like Adrenomed and Fraunhofer, and, although not visited during the GEM, the Helmholtz-Zentrum für Infektionsforschung.

5.2.9.3 What

In fact the mentioned German research institutions and companies should be introduced to UK companies, (contract) research organisations, hospitals and analyses laboratories in an effective way.

5.2.9.4 Next step

A next step could be to enrol the involved German and UK in a novel UK-German call for alternatives antimicrobials research.

5.2.10 Stimulate joint research on AMR (10)

5.2.10.1 Why

Research into novel antimicrobials, alternatives and diagnostics remains the starting point to fuel the product pipeline.

5.2.10.2 How

The German Fraunhofer and the UK Catapult institutes are comparable research institutes. Although not intensively studied, the first impression is that there is limited overlap in the research activities. It is expected that there will be quite some complementary activities and possibilities for synergy when the institutes would collaborate.

5.2.10.3 What

In fact the German and UK institution should be exposed to each other and given the opportunity to work out and initiate collaborations.

5.2.10.4 Next steps

The best way to explore complementarity and synergy would be to enrol the institutes, as well as other research institutes in an open, bilateral German-UK call.

5.2.11 Support development coherent German AMR strategy (11)

5.2.11.1 Why

In order to be effective, a country must have a solid, clear-cut and coherent AMR strategy which is enrolled in an effective and unequivocal manner. The GEM has given the impression that Germany lacks such unequivocal strategy and that the country, for several reasons, is not able to effectively implement it.

5.2.11.2 How

The UK has shown to be able to set up and implement an effective AMR strategy. It makes sense for the UK to share its experiences with Germany and for Germany to learn from the UK.

5.2.11.3 What

The UK could in fact advise Germany with respect to DART, the German national antibiotics strategy.

5.2.11.4 Next step

The next step would be to set up one or more round table conferences with Germany (Ministry of Health, RKI, DZIF) and the UK (NHS) to discuss the appropriateness of such approach.

5.2.12 Support setting up a national AMR Hub (compare China)(12)

5.2.12.1 Why

In order to be effective, a country should not only have a solid, clear-cut and coherent AMR strategy but also a national AMR Hub. Germany is lacking such a national coordination centre.

5.2.12.2 How

The UK has shown that it is able to support countries in setting up AMR Hubs (like in China). This experience may be very valuable for Germany.

5.2.12.3 What

The UK could, together with Germany, work out the strategic plans for such national AMR and thereby bring in its own international experience.

5.2.12.4 Next step

The next step would be to set up one or more round table conferences with Germany (Ministry of Health, RKI, DZIF) and the UK (NHS) to discuss the appropriateness of such approach.

5.2.13 Improve UK German familiarity (innovation, business)(13)

5.2.13.1 Why

AMR is clearly a global and not a national challenge demanding for national, international and transnational collaboration. The possible collaborations between Germany and the UK may potentially reach much further than mentioned in this report. Also entirely new collaboration opportunities between the two countries will arise in the future.

5.2.13.2 How

The two countries Germany and the UK, as far as AMR is concerned, work in pretty much in isolation from each other. Apart from what is suggested in this report the two countries should work on exploring and utilizing common more (and future) ‘AMR grounds’.

5.2.13.3 What

In order to utilize the full potential of both countries when it comes to AMR the stakeholders and networks should be much better unlocked, made reachable and made intertwined.

5.2.13.4 Next step

The next steps would be to work on making the AMR stakeholders in both countries more known and familiar to each other by means of advertising, organising events, etc.

5.3 Next steps at the short term

It is obvious that some of the objectives can be combined into follow up steps. In fact, the following next steps are then proposed:

5.3.1 One or more Round Tables in the UK and/or in Germany on improving prevention [I]

To meet the objectives:

- Reinforce German capacity building in LMIC's (Objective 1)
- Support German implementation stewardship programs in German Healthcare centers (Objective 3)
- Support creating awareness on AMR in German hospitals (Objective 4)

5.3.2 A UK mission to Germany on improving use of German data [II]

To meet the objectives:

- Capitalise on UK (big) data expertise and infrastructure (Objective 2)

5.3.3 A German mission to UK for accelerating the development of German diagnostics [III]

To meet the objectives:

- Co-develop / help testing German diagnostics tools by UK universities and SME (Objective 5)
- Help commercialising German diagnosticss in UK (Objective 6)

5.3.4 Feasibility study on the possible added value of companion diagnostics [IV]

To meet the objective:

- Explore opportunities for companion diagnostics (Objective 7)

5.3.5 Round Table on developing a more national AMR strategy in Germany [V]

To meet the objectives:

- Support development of a coherent German AMR strategy (Objective 11)
- Support setting up a national German AMR hub (Objective 12)

5.3.6 Profile UK AMR within the German AMR space [VI]

A good way to do so may be by attending the Biocom AMR Conference in 2020. Profiling the UK can be in various ways including co-hosting, sponsoring, setting up a dedicated UK (partnering) event, advertising and/or supporting UK delegates to attend (Objective 13).

Leaving by train, plain, metro or otherwise at the end of the mission

5.4 Next steps short term (schematically)

The proposed short term objectives can be schematically represented as follows:

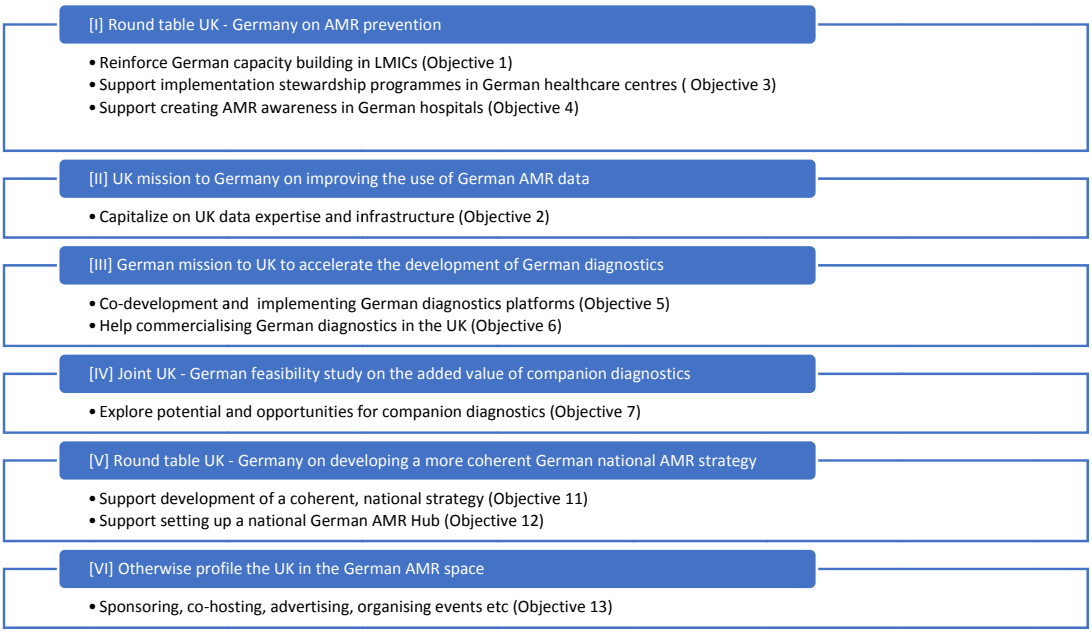

Figure 2; schematic representation follow up steps

[optional table; if useful..]

Key Strategies:		Strategic objectives:	German parties include:
Improved Prevention	1	Reinforce German capacity building in LMIC	RKI, Charite
	2	Capitalize on UK (big) data expertise and infrastructure	RKI, Charite, Infectognostics, DZIF
Improved Stewardship	3	Support German implementation stewardship programs	German Hospitals
	4	Support creating awareness on AMR in German hospitals	German Hospitals
Improved Diagnostics	5	Co-develop / help testing German diagnostic tools	Bosch HS, Blink, Qiagen, Fraunhofer
	6	Help commercialising German diagnostics in the UK	Bosch HS, Blink, Qiagen, Curetis
	7	Explore opportunities for companion diagnostics	Tbd
Novel Antimicrobials	8	Capitalize on UK contract (clinical) development	AiCuris
Alternative Strategies	9	Explore opportunities for UK German collaboration	Fraunhofer, Adrenomed
General	10	Stimulate joint research on AMR	Fraunhofer
	11	Support development coherent German AMR strategy	Ministry of Health
	12	Support setting up a national AMR Hub (compare China)	Ministry of Health
	13	Improve UK German familiarity (innovation, business)	All German stakeholders in AMR

5.5 Next steps at a longer term

5.5.1 Joint UK-German call to accelerate AMR-related research in Germany and the UK

Objectives:

- Capitalise on UK contract (clinical) development infrastructure (Objective 8)
- Explore opportunities for UK German collaboration on alternative antimicrobial strategies (Objective 9)
- Stimulate joint UK German research in general and between Catapult and Fraunhofer in particular (Objective 10).

Annex 1 – Abbreviations

AMR	Anti-Microbial resistance
ARDIS	African and Asian Resilience in Disaster Insurance Scheme
B2B	Business to business
BSAC	British Society for Antimicrobial Chemotherapy
CARA	Conscience of AMR Accountability
CARB-X	Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator
CDC	US Center for Disease Control and Prevention
COMBACTE	Combatting bacterial resistance in Europe
DART	Deutsche Antibiotika Resistenz Strategie
DZIF	Deutschen Zentrum fur Infectionsforschung
EARSNET	European Antimicrobial Resistance Surveillance Network
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
FAO	Food and Agriculture Organisation
GARDP	Global Antibiotic Research and Development Partnership
GDP	Gross Domestic Product
GP	General Practitioner
IBMT	Fraunhofer Institute for Biomedical Engineering
IMI	Innovative Medicines Initiative
IZI-BB	Fraunhofer-Instituts für Zelltherapie und Immunologie Bioanalytik und Bioprozesse
JPIAMR	Joint Programming Initiative in AMR
JPIAMR VRI	JPIAMR Virtual Research Institute
KTN	Knowledge Transfer Network
LMIC	Low and Middle Income Countries
MRC	Medical Research Council
MRSA	Methicillin-resistant Staphylococcus aureus
NHS	National Health Service
OECD	Organisation for Economic Co-operation and Development
OIE	Organisation for Animal Health
PHE	Public Health England
RKI	Robert Koch Institute
SARIC	Surveillance AMR in Intensive Care Units
SBRI	Small Business Research Initiative
SIG	Special Interest Group
SME	Small and Medium-sized Entity
UKRI	United Kingdom Research and Innovation
UN	United Nations
WHO	World Health Organisation

Annex 2 – List of UK and Germany Participants

UK

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