Commercialising antimicrobial resistance (AMR) solutions

Final report release date: March 2026

Based on research and stakeholder consultations conducted in Q3/Q4 2024

dandolopartners

Foreword

The *Commercialising Antimicrobial Resistance (AMR) Solutions report* was undertaken to understand the type, accessibility, and relevance of support available in Australia for researchers and/or small-to-medium enterprises to commercialise solutions to minimise the impacts of AMR across sectors. The report was undertaken by dandolo partners and the former Minimising AMR Mission, which was codeveloped by the Departments of Health, Disability and Ageing, and Agriculture, Fisheries, and Forestry. A project steering committee with representatives from DISR, Department of Education, CSIRO, and Science Technology Australia provided input and feedback.

Innovative solutions are a key tool to combatting AMR in Australia. To ensure innovative AMR solutions are widely available for use by individuals and businesses operating in the human health, primary industries, and the environment sectors, innovators need an effective system that supports research translation, commercialisation, and market access. In Q3, 2024, the team undertook desktop research of the Australian companies that are commercialising AMR solutions. This informed the subsequent stakeholder consultations with researchers and SMEs commercialising technology as well as organisations that provide commercialisation support programs. The report identifies barriers for commercialisation of products related to AMR and gaps in the services and infrastructure that support commercialisation. It also provides recommendations to support commercialisation including developing a potential roadmap to address AMR through coordinated investment and action.

Introduction

Commonwealth Scientific and Industrial Research Organisation (CSIRO) commissioned dandolopartners (dandolo) to capture the barriers faced by researchers and SMEs commercialising AMR solutions and identify gaps in the support environment.

Background

The economic and social benefits from antimicrobial resistance (AMR) solutions are significant. Recognising this, CSIRO and the then Departments of Health and Aged Care and Agriculture, Water and the Environment, collaborated on a 'Minimising AMR Mission' to halt Australia's rising death rate and reduce the economic burden of AMR by 2030.

Developing innovative solutions is key to addressing AMR, however there are challenges in bringing these solutions to market. CSIRO engaged dandolo to identify and explore the barriers to commercialising AMR solutions and identify gaps in support offerings.

This report

The purpose of this report is to capture the common needs and barriers to commercialising AMR solutions in Australia. This report will contribute to CSIRO and other stakeholders' considerations for how the Australian ecosystem can better support and enable the translation and commercialisation of AMR solutions.

A framework was developed to facilitate identification of the different types of AMR solutions and the organisations that develop them and to map the commercialisation pathway. This approach reflects the diversity of AMR solutions and the different challenges experienced along the research translation journey.

The report highlights key themes from consultations with stakeholders and offers recommendations for next steps to support commercialisation.

Report structure

Context: What is antimicrobial resistance?

Antimicrobial resistance is a growing threat to the health and economy at a global scale.

Antimicrobial resistance, or AMR, occurs when bacteria, viruses, fungi, and parasites evolve to resist the effects of medications that once effectively treated infections they cause.

This resistance arises from genetic changes in these microorganisms, often driven by overuse or misuse of these medications in human health, agriculture, and livestock farming.

Key impacts of AMR include, but are not limited to:

Increased morbidity and mortality

AMR makes infections harder to treat, which leads to prolonged illness and higher chances of disease spread within healthcare settings and the broader community. It also results in higher mortality rates, with AMR being directly responsible for approximately 1.27 million deaths worldwide in 2017, surpassing deaths from HIV/AIDS or malaria.[1] A recent Lancet study predicts a drastic rise, with cumulative global deaths between 2025 and 2050 expected to reach 39 million —equivalent to three deaths per minute.[2]

Escalating healthcare costs

Treating drug resistant infections is more expensive than treating non-resistant ones, as patients often require longer hospital stays, more intensive care, and the additional use of expensive last-line or experimental medication. This could have significant impacts on the global economy, with the World Bank estimating that AMR could result in a loss of 3.8% of global GDP by 2050 if left unaddressed.[2]

Threats to modern medicine

The loss of effective antibiotics and antivirals jeopardises modern medicine, turning routine healthcare into high-risk practices. For example, to safely carry out surgeries, including transplants and other invasive treatments, effective antimicrobials are needed to minimise the risk and/or treat infection.[3]

This means AMR could undermine decades of medical progress and limit the options for future medical advances.

[1]https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance
[2]Global Research on Antimicrobial Resistance (GRAM). *Antibiotic resistance has claimed at least one million lives each year since 1990: GRAM.* GRAM. Retrieved 1st November 2025, from https://www.tropicalmedicine.ox.ac.uk/gram/news/antibiotic-resistance-has-claimed-at-least-one-million-lives-each-year-since-1990-gram
[3]https://www.worldbank.org/en/topic/health/brief/antimicrobial-resistance-amr

Context: Why commercialising AMR solutions is important

Innovative solutions are a key tool in combatting AMR.

Addressing AMR requires action at all levels – including researchers, governments, healthcare providers, individual clinicians, and the broader public. **Shifting current behaviours** is a necessary step. This includes activities like promoting responsible antibiotic usage, disseminating information about AMR to the public, and increasing vaccine uptake. However, this will only get us so far.

Efforts to combat AMR need to outpace the rapidly evolving resistance of bacteria, viruses and other pathogens. The development of **new and innovative medical and scientific solutions** is a critical tool in addressing AMR. This include new:

- Antimicrobials, such as antifungals and antibiotics
- Diagnostic tools, such as diagnostic medical imaging and wearable health monitors
- Environmental technologies, such as water treatment systems and air quality monitors
- Materials, such as antimicrobial surface coatings and packing materials.

However, we're not seeing the amount, breadth and uptake of solutions needed to effectively address AMR.

More innovative AMR solutions will be developed if there is a smooth pathway to commercialisation.

To make effective AMR solutions widely available for use in healthcare, agriculture, personal use, and other relevant contexts, innovators need an effective system of bringing solutions to market. This process is called research translation or **commercialisation**.

This involves:

- ***Demonstrating the scientific efficacy****, such as initial research, conducting clinical trials, obtaining regulatory approvals.*
- ***Demonstrating commercial viability****, such as establishing a sustainable business model, securing funding, navigating distribution channels.*

There are many steps in the pathway to commercialisation, and many barriers. However, a smooth journey to commercialisation, where these barriers are removed, minimised or mitigated, will help ensure that new solutions to address AMR have the best chance to:

1. Transition from an idea to a solution
2. Reach market
3. Remain available to its relevant audience even through fluctuating market demands
4. Ultimately, contribute to the sustained fight against AMR.

Examples of innovative solutions developed to combat AMR include:

Vaxxas

What is it? Vaxxas is commercialising a new vaccination technology aimed at significantly enhancing the effectiveness of current and next-generation vaccines.

The company's HD-MAP technology is a needle-free patch with thousands of vaccine-coated microprojections that, when applied to the skin for a few seconds, efficiently delivers the vaccine to immune cells just below the surface.

How is it an AMR solution? Vaxxas aims to increase vaccine uptake and reduce disease transmission by providing an alternative to needles and syringes. This approach emphasises prevention to lower the risk of disease and infection, potentially reducing reliance on reactive treatments like antibiotics and helping to address rising rates of AMR.

Flowcrete (Flowfresh)

What is it? Flowcrete is a manufacturer of floor coating solutions. Flowcrete has developed a new generation of antimicrobial flooring in partnership with Polygiene®, called Flowfresh. The antimicrobial agent is homogenously distributed throughout every Flowfresh system to enhance on-site hygiene levels by actively targeting bacteria in contact with the floor.

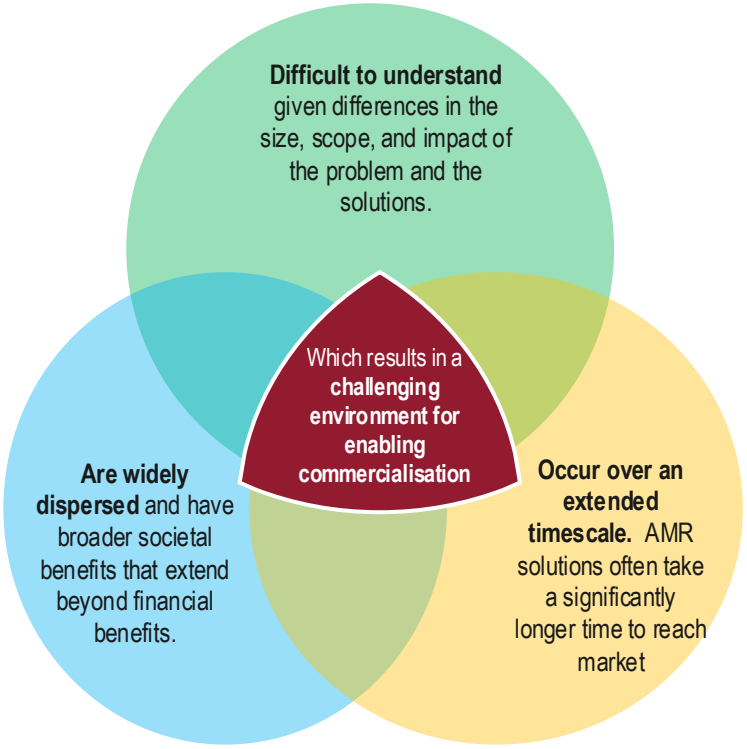
How is it an AMR solution? Flowcrete has designed a solution, Flowfresh, that works to combat AMR through antimicrobial flooring. Antimicrobial flooring prevents mould and mildew growth and is easy to clean and maintain, thereby infection risk.

Executive summary

Findings on a page

Lack of understanding, dispersed benefits and typically longer time to market create overarching barriers to commercialisation.

Many organisations face **overarching barriers** to commercialising AMR solutions. These barriers exist because the benefits of AMR solutions are often:



This exacerbates common barriers to commercialisation, including:

- Access to funding is limited and not always fit-for-purpose
- There is insufficient access to expertise and networks
- There is insufficient access to scientific and manufacturing infrastructure
- Regulatory pathways are complex and difficult to navigate

This leads to a loss of opportunities and loss of expertise

There is a need to increase awareness and understanding of AMR, upskill existing support structures, and make a case for further investment.

Summary of recommendations

While a full gap analysis of supports available for commercialising AMR solutions was out of scope, this project has identified a clear need for public and private actors to prioritise combatting AMR, address barriers to commercialisation, and adequately respond to the scale and scope of the problem.

In summary, the report recommends:

1. Increasing awareness and understanding of the size, significance and relevance of the AMR problem.
2. Producing a strategic roadmap to prioritise and address AMR through coordinated investment and action.
3. In parallel with (1) and (2) Consider additional low-cost initiatives to raise awareness of AMR and increase targeted support.

Methodology and conceptual framework

Methodology and scope

dandolo and CSIRO collaborated to undertake desktop research and stakeholder consultations, to identify key insights and present recommendations.

Methodology

Project establishment
Involved a kick-off meeting and conceptual framework workshop with CSIRO.

Desktop research
Collated and synthesised research into needs, gaps, and barriers to commercialisation of AMR solutions to inform stakeholder consultation.

Stakeholder interviews (10)
Conducted interviews with innovation ecosystem stakeholders[1] and select researchers / SMEs. Designed to provide a system level perspective of barriers and needs to inform outputs and further consultation.

Online discussion forum
Designed to reach a broad range of researchers / SMEs to test and quantify hypotheses on AMR solution commercialisation.

Final report
Captured and synthesised key findings from consultation and desktop research to identify needs and commercialisation barriers and provide recommendations.

Project steering committee[2] meetings to test hypotheses and findings throughout the project.

Scope of the final report

The purpose of the report is to identify the common needs and barriers to commercialise AMR solutions in Australia.

The report does:

- ✓ Identify common barriers across AMR solution types.
- ✓ Identify barriers specific to each solution type, where possible.
- ✓ Discuss implication of these barriers on AMR solution commercialisation.
- ✓ Draw on stakeholder consultation and initial research provided by CSIRO.
- ✓ Capture stakeholder perceptions of gaps in the support available and requirements for additional support.
- ✓ Identify a 'long list' of options for further support.
- ✓ Provide recommendations on next steps based on findings.

This may lead to further work exploring gaps and potential opportunities, which sat outside of scope of the project.

The report does not:

- ✗ Delve deeply into solution types to capture specific barriers.
- ✗ Provide a gap analysis of supports and services for AMR solutions.
- ✗ Conduct extensive additional desktop research to further validate stakeholder perspectives.
- ✗ Provide recommendations on specific supports that the public sector should fund.

[1] Refer to slide 8 for further information on stakeholders consulted
[2] Refer to Appendix 2 for the list of Steering Committee members

Overview of conceptual framework

We developed a conceptual framework[1] capturing the key characteristics that influence the needs, barriers, supports, and gaps in the commercialisation of AMR solutions. This guided our initial thinking and consultation around barriers to commercialisation.

Commercialisation stage

We used Technology Readiness Levels (TRLs) to define each commercialisation stage. TRLs are used globally across a range of industries, sectors, and government.

Solution type

Pharmaceuticals

Synthetically- and biologically-derived drugs, to either treat or prevent AMR infections in humans or animals (including vaccines)

Medical devices and diagnostics

Instruments, apparatuses, machines, and other similar articles intended for use in diagnosis, prevention, monitoring, treatment, or alleviation of AMR-related issues

Materials

Barriers, coatings, and chemical disinfectants that provide direct benefits in mnimising AMR

Envirotech

Engineering and technological devices and processes that reduce AMR impacts in the broader environment

Software and AI

Digital solutions to support AMR-related activities in medical, professional, and/or personal contexts

Consulting and information services

Providing expert advice, data, and strategies to manage and mitigate the impact of AMR. This includes policy advice in the AMR space

[1]Refer Appendix 1 for further information on elements of the conceptual framework

Constraints and limitations

This work focuses on capturing the key barriers faced across the AMR solutions 'sector'. Despite best efforts to consult widely, findings are based on a limited sample size, although they are consistent with the bulk of existing literature on barriers to commercialisation. Insights in this report should be read in that context.

Limitation	Description	Implications
This research deliberately focused on breadth rather than depth	Given the limited scope of this project, a trade-off was made to focus on breadth of solution type rather than deep-diving into specific solution types.	This research represents an early step in characterising the distinctive challenges that AMR solutions face in Australia. Further research would be required to explore specific commercialisation challenges within solution types at different commercialisation stages.
Small sample size	We directly consulted a small pool of stakeholders, which include: • 11 researchers and SMEs who develop AMR solutions. These consultations were done through interviews and an online discussion forum (a further 12 completed a pre-discussion forum survey about their organisation and their AMR solution but they did not participate in the forum). • Seven representatives from broader innovation ecosystem organisations with AMR interests. For example, venture capital firms, peak bodies / associations, accelerators / incubators. • Internal AMR / innovation experts within dandolo, CSIRO, and the project steering committee. However, the stakeholders we did consult with were very engaged, generous with their contributions.	Insights may be more representative of the profile of respondents, which tended to: • Be in human-focused health, and • Strongly identify as being in the AMR space and aligned with the AMR mission. Despite a small sample size, stakeholders were broadly aligned about the major barriers in commercialising AMR solutions. We expressly asked stakeholder to focus their perspectives on insights that are specific to AMR solutions as opposed to challenges of the broader innovation space. However, we acknowledge that findings reflect this sample.
Some solution types were under-represented	The breadth of actors in the AMR space is broad, but we mainly had engagement from a subset of human-focused sectors / industries. We didn't receive any engagement with AMR solutions that: • Are in the enviro-tech sector. • Develop AMR materials. • No longer exist, i.e., we only spoke to solutions who haven't folded. • Are developers of products / services that provide AMR-reduction benefits, but where addressing AMR is not a core focus.	
Challenge capturing barriers against discrete commercialisation stage	When characterising the challenges they face in commercialisation, stakeholders often focused on the ones that: • They are currently facing, and / or • The most significant / consequential challenges they had faced throughout their commercialisation journey	We were able to capture the most critical issues that developers of AMR solutions face but are limited in attributing them to specific commercialisation stages or phases of their commercialisation timeline.

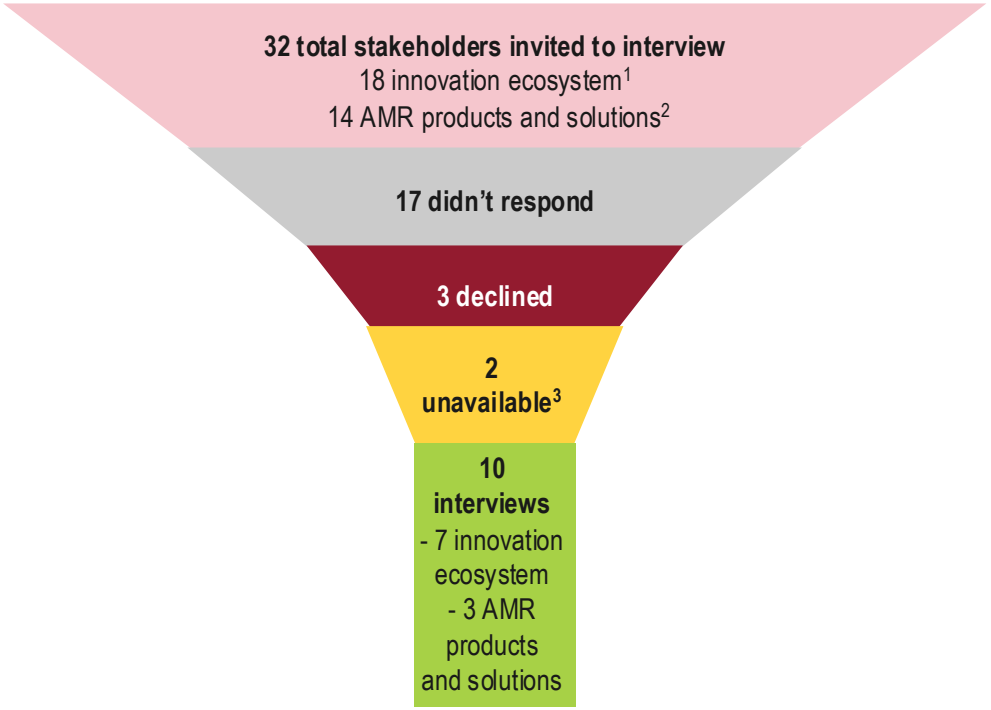
Despite these limitations, we are confident in our findings because:

- Stakeholders were broadly aligned in the major barriers faced in commercialising AMR solutions.
- Where possible, we balanced consultation insights with independent research desktop research of existing evidence.
- Interviews and online discussion forums were thorough and added deep and nuanced insights.

Stakeholder engagement

dandolo and CSIRO collaborated to invite a diverse range of stakeholders for interviews and online discussion forum participation. However, there was limited engagement from some sectors.

For interviews, 53% of the 32 contacted stakeholders did not respond, and 9% declined.

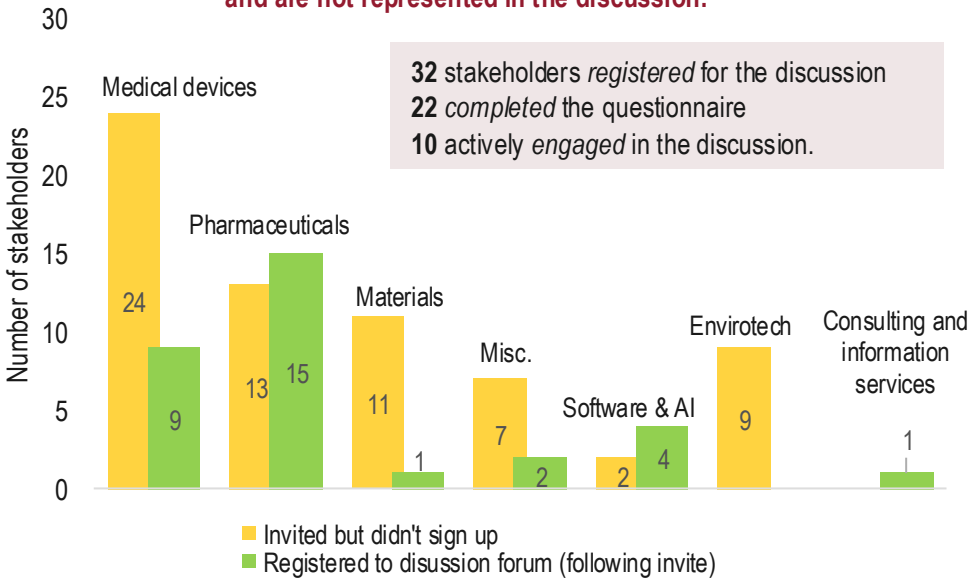


For online discussion forums (ODFs), dandolo and CSIRO collaborated to invite stakeholders to engage in the conversation.

We reached stakeholders through various channels, utilising existing networks and connections to maximise engagement. These avenues included:

- Inviting stakeholders directly via email.[4]
- dandolo worked with AAMRNet and MTPConnect to distribute the ODF invite through their networks.
- dandolo contacting incubators and accelerators in key AMR R&D areas to share the ODF invite with their networks.
- CSIRO posting about the ODF on LinkedIn.

We invited 98 stakeholders from various sectors. Three sectors did not participate and are not represented in the discussion.[5]



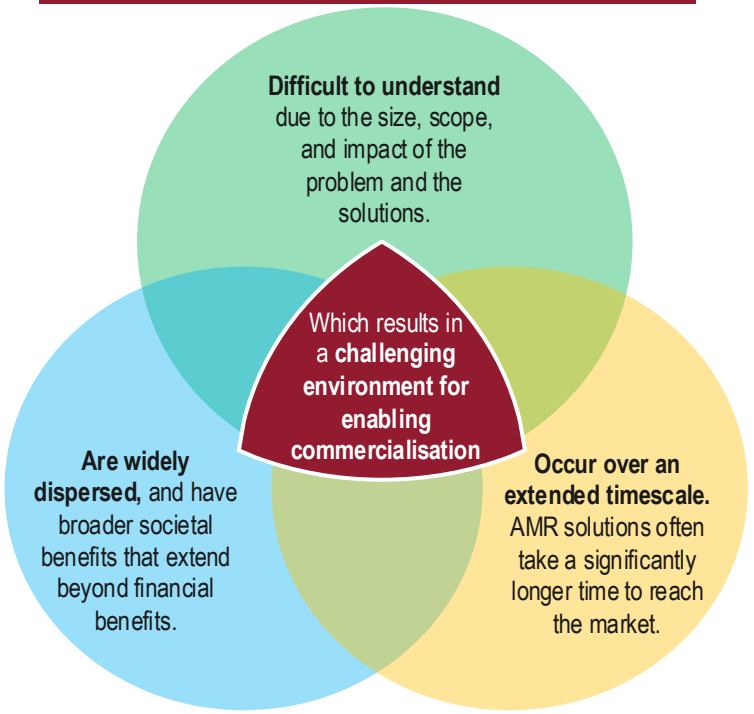
[1] Innovation ecosystem stakeholders included: incubators, accelerators, VCs / investors, and other (peak bodies, non-for-profits)
[2] AMR products and solutions include: medical devices / diagnostics, pharmaceuticals, biotech / agtech, cleaning solutions, materials and software & AI
[3] Unavailable during fieldwork period
[4] A total of 98 stakeholders were invited via email (this involved CSIRO sending an initial warm introduction email, followed by dandolo's direct invitation to stakeholders); 32 registered; 22 stakeholders completed the questionnaire; and 10 engaged in the discussion.
[5] Not all participants that registered participated in discussions on the forum. 10 participants engaged in the forum in total (Pharmaceuticals: 4; Medical devices: 3; Software and AI: 2; Misc: 1)

Barriers to commercialising AMR solutions

Key findings

Lack of understanding, dispersed benefits and typically longer time to market creates a challenging environment for enabling commercialisation of AMR solutions, which exacerbates common barriers to commercialisation.

Many organisations face **overarching and long-term barriers** to commercialising AMR solutions. These barriers exist because the benefits of AMR solutions are often:



Slides 13 – 14

This exacerbates more **AMR specific barriers** to commercialisation, including:

- Access to funding is limited and not always fit-for-purpose — **Slides 15-16**
- There is insufficient access to expertise and networks — **Slides 17-18**
- There is insufficient access to scientific and manufacturing infrastructure — **Slide 19**
- Regulatory pathways are complex and difficult to navigate — **Slide 20**

This leads to a loss of opportunities and loss of expertise

Slides 15 – 20

AMR is difficult to understand

It is difficult to understand and appreciate the scope and reach of the AMR problem and the range of potential solutions, which contributes to a challenging environment for commercialisation.

It is difficult to understand the size, scope, and impact of AMR

- The impact of AMR is widespread – affecting the health of people, animals, plants, impacting health outcomes and food security.[1] Antibiotic resistance has caused at least one million deaths annually since 1990, and a recent Lancet study predicts a drastic rise, with cumulative global deaths between 2025 and 2050 expected to reach 39 million — equivalent to three deaths per minute.[2]
- The general scale of the problem is well-documented but the sheer scope and reach of the problem has not received a proportionate response. The widespread nature of the problem makes it hard to communicate the size and impact and the urgent need to come together to address it.
- Stakeholder groups integral to supporting the development and adoption of AMR solutions—such as funders, regulators, clinicians, and the general public—clearly lacked understanding as to how their solutions intersect with AMR.
  - For example, one organisation that developed a pharmaceutical to treat a cancer had made little to no consideration of its intersection with AMR, despite AMR presenting significant risks to the cancer patients.
- This demonstrates how difficult it is to understand, and / or appreciate, the scope and reach of the problem.
- The lack of understanding among stakeholders contributes to the overarching barriers to commercialisation associated with AMR solutions.

"The market focuses more on treatment after incidents than on risk elimination. Discrepancies in decision-making and funding access create challenges for improving airborne infection control, especially for AMR pathogens." – Developer of an AMR solution

It is difficult to understand the scope of solutions

- A common understanding of how best to combat AMR has focused on treatment, particularly misuse and overuse of antibiotics, and developing 'last line of defence' solutions, as the way to solve the problem. There is less of a focus on other ways to combat AMR e.g., through prevention or non-antibiotic solutions.
- AMR-led solutions are broad and not just limited to medical solutions. They also include solutions for human and animal health, food production, and agriculture, however, these are less well known in the AMR space. There is untapped potential in these industries, which are well-positioned to contribute to combating AMR, but may not consider themselves as part of the AMR solution landscape or recognise the potential of their products in this space. For example, CSIRO identified several organisations in the materials and envirotech sectors that are relevant to AMR, but only those in the human health sector responded to the invitation to consult. This may suggest that other sectors do not identify as strongly with AMR.
- Non-human health fields trying to commercialise AMR solutions may experience additional barriers given there are fewer sector-specific support structures available that understand the AMR context. The challenges dandolo faced in engaging these sectors for consultation suggest that the non-human health sectors may lack understanding of their association and/or contribution to AMR.

"Pharma companies, investors, government, and clinicians misunderstand what sits where, and which tool is used to solve which problem. For example, an investor might want to invest in antibiotics, but if they don't try to address resistance breakers, the same issues will manifest again." – Developer of an AMR solution

[1] https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance
[2] Global Research on Antimicrobial Resistance (GRAM). *Antibiotic resistance has claimed at least one million lives each year since 1990: GRAM.* GRAM. Retrieved 1st November 2025, from https://www.tropicalmedicine.ox.ac.uk/gram/news/antibiotic-resistance-has-claimed-at-least-one-million-lives-each-year-since-1990-gram

Benefits are often long term and dispersed

The benefits of AMR solutions are often longer-term and dispersed, with spillover benefits that extend beyond financial returns. This reduces natural market incentives to invest in commercialising AMR solutions.

The benefits of AMR solutions often occur over the longer-term. This is because:

There can be a long time-to-market for AMR solutions,[1] particularly for deep tech solutions with disruptive technologies.

The commercialisation pathway for AMR solutions can be long-term, particularly those developing deep tech solutions with disruptive technologies.[2] These technologies tend to:

- Require more time in research and development.
- Face considerably protracted and additional regulatory hurdles.

This further extends already long lead times for realising impact.

"AMR timescales are likely much longer than other areas and hence that is an additional barrier in securing commercialisation investments from VCs." – Developer of an AMR solution

Solutions can have a slower uptake in the market

Some solutions – particularly 'last line defense' solutions – are only intended to be used once other methods have been exhausted. This means they are less frequently used, extending the timeframe to see commercial return. Current reimbursement models do not meet the needs of these solutions. An example of a novel reimbursement models seeking to address this is in the UK where the payment for antibiotics is de-linked from the volume of sales and instead an annual fee is paid to the company based on the value of the antibiotic to public health[3].

"It all flows back to a completely [flawed] market for the entire life cycle of developing a drug." – Innovation ecosystem stakeholder

There are cumulative benefits to addressing AMR

The cumulative and long-term benefits of multiple AMR solutions operating across sectors will have the most impact on curbing AMR. For example, the compounding impacts of societal reduction in antibiotic use, technology to enable good antigen detection, improved farming pharmaceuticals, and other AMR considerations can have more impact than developing a last-line defense antibiotic (noting the critical role that antibiotics play in the health ecosystem).

Cumulative benefits:

- Can take a long time to manifest
- Can be felt everywhere, but not attributable to a single solution
- Can require collective and coordinated efforts across multiple sectors.

"Antibiotics are in a unique situation where that uptake is intentionally supressed through AMR stewardship processes. If you bring a new antibiotic to market, there's going to be no resistance, so there is no use for AMR early in that context. By the time you do, the patent has expired and the generics are in the market." – Innovation ecosystem stakeholder

The benefits of minimising AMR are dispersed and have a broader societal impact

Successful commericialisation and deployment of AMR solutions have spillover benefits

- Benefits extend beyond the direct point of use for an AMR solution. For example, the use of an antibiotic surveillance tool in agriculture and food production can reduce the spread of AMR infections from animals to humans.[4] The indirect benefit of the AMR solution is dispersed and has a broader impact than that single point of contact.
- The value of AMR solutions extend beyond financial benefits, which reduces natural market incentives and contributes to the overarching barriers to commercialisation.
- For these reasons, the total net benefits of an AMR solution can be hard to quantify – both financially and in their contribution to tackle AMR more broadly.

"Most VC funds are not a good fit for us, because our applicability is so broad. They want us to fit within a narrow mandate, and within that mandate seek niche markets." – Developer of an AMR solution

[1] This is typically 10 -15 years for antibiotics, or 7-15 years for disruptive AMR med tech device. https://www.bms.com/assets/bms/australia/documents/press-releases/FINAL-Full-Guide-medicines-access.pdf
[2] Bristol Myers Squibb Australia. (2021). *A guide to medicines access.* Retrieved 1st November 2025, from https://www.bms.com/assets/bms/australia/documents/press-releases/FINAL-Full-Guide-medicines-access.pdf
[3] https://www.healtheuropa.com/extending-the-uks-leadership-with-an-antibiotic-subscription-model-to-tackle-amr/116709/; https://www.abpi.org.uk/media/news/2023/november/uk-antibiotic-subscription-model-key-to-supporting-antibiotic-investment/
[4] https://www.amr.gov.au/what-you-can-do/agriculture-and-industry#what-role-do-food-animals-play-in-amr

Access to funding (1)

Access to funding is a key challenge for the commercialisation of AMR solutions. This is exacerbated by unclear incentives to invest in AMR solutions, which results in insufficient dedicated funding to address the barriers to commercialisation and the scope of the problem.

The financial return on AMR solutions can be moderate and disproportionate to the potential societal benefits, impacting access to funding.

Investing in AMR solutions can be less attractive to funders, such as VCs or private equity firms, who are ultimately seeking timely commercial returns on their investments. These technologies require significantly more funding and have a higher risk profile, impacting financial viability.

When funders *are* interested in supporting AMR solutions, they may be more likely to:

- Fund 'first line defense' solutions where the level of application is broader, even if there isn't as much of an AMR product/service gap in that space.
- Seek to compartmentalise AMR solutions into a single product or to address a single problem, when a scientific innovation may have multiple applications across sectors and therefore have broader benefits for curbing AMR,
- Prioritise commercial opportunities that bring the potential of a quick exit, which doesn't align with many AMR organisations whose impacts are longer term and potentially more dispersed.

Lack of dedicated AMR funding streams

- The proportion of public funding dedicated to addressing AMR does not reflect the scale and breadth of the problem.
  - For example, of the approximately $650 million in Medical Research Future Fund (MRFF) funding distributed in 2023[1], only 6 million was dedicated to supporting research to address AMR[2]. This is less than 1% of the total pool of funding.
  - When scheduling consultations for this project, three of the innovation ecosystem stakeholders approached declined offers to interview, citing the following reasons:
    - AMR is not a focus in their healthcare investment strategy
    - Do not work in the AMR space and cannot help.

"You're up against everyone else …and there's no special calls for AMR … there are a lot more directed funding opportunities [overseas] than there are certainly within Australia." – Innovation ecosystem stakeholder

"AMR diagnostics are not generally reimbursed independently of the bacteria that they are investigating so the introduction of any AMR diagnostic is viewed as an additional cost to the laboratory that is offering them. If there is a reimbursement for AMR testing it is generally very low." – Developer of an AMR solution

"We want to build the R&D capability to build the longer-term value and potential. We want to build a company where you can develop multiple licences and products … We can't go to a VC because they'll pigeonhole and try to turn us into a business. Difficult to go to the stock market, because they are driven by a one-product approach." – Developer of an AMR solutions

[My organisation] "looks for areas where the benefit of a novel intervention is significant. For example, consider where an infection can impact surgery and be life threatening. In that context where a novel product can get a premium as a first-line defence, and we can prove that it's superior to existing therapies, then that opportunity is attractive to us." – Venture Capital firm

[1]https://www.health.gov.au/sites/default/files/2024-09/medical-research-future-fund-report-on-chief-investigator-data.pdf
[2]https://www.health.gov.au/news/mrff-6-million-for-research-into-antimicrobial-resistance-and-reducing-the-incidence-of-hospital-infections

Access to funding (2)

Nearly all stakeholders commercialising AMR solutions say that the scale of funding available is insufficient – especially beyond the early stages of commercialisation. Some stakeholders who accessed funding faced challenges around funding timing.

Scale of targeted funding is not sufficient and there are restrictions on its use

Though access to funding is a commonly mentioned barrier to commercialisation in any context, the level of targeted funding available to commercialise AMR solutions doesn't match the need.

Whilst some public funding options are available to innovators to support early-stage research, there are specific areas where there are limited funding options and funding scale, including:

- Funding clinical trials
- Funding the development of infrastructure

These constraints incentivise applying for the 'lowest-hanging fruit', which risk compromising an innovative solution's overall impact on the curbing AMR mission in order to give it the best chance of receiving funding.

Challenges with timing of funding

One stakeholder shared that there was a significant amount of time between being awarded government funding and receiving it. This caused operational challenges and delays to the whole commercialisation pathway because they were not able to progress until they had access to the funding. They attributed this delay to:

- A lack of understanding of what is required by firms to address AMR
- A lack of understanding of the general needs of start-ups and developing innovative solutions
- Timing of funding delivery being influenced by external factors, such as preferred time to announce

Delays in accessing funding and / or inability to source funding for these critical stages of commercialisation is a significant barrier to commercialisation and can prevent AMR solutions from reaching market altogether.

"Government needs to understand the scale of the process and project and need to provide funding to enable that scale. And if we are supported by State and Federal funding, it gives confidence for banks to get on board." – Developer of an AMR solution

"We have a product (with demonstrated results) but lack the funding to get through clinical trials." – Developer of an AMR solution

"Small companies benefit from the grants available, and you might get $1 million in funding. You may make it to phase 1 or 2 but then the bills start racking up and then the funding dries up." – Innovation ecosystem stakeholder

"Timing of funding often does not suit … We were awarded government funding for technology. We couldn't order the machinery we needed it until finalised, and it took 18 months of waiting for documentation to be finalised for approval. 18 months is 10 years in start-up. Had I known I would have supplied the money myself." – Developer of an AMR solution

"[I would like to see] a funding stream for validating early-stage, high-risk solutions that offers quick turnaround times and easy accessibility." – Developer of an AMR solution

Barriers to commercialisation: Expertise

There is a lack of access to expertise and advice for commercialising AMR solutions, which is exacerbated by a shrinking pool of experts in Australia. There were mixed views about access to AMR networks for commercialisation support.

Lack of expertise to provide AMR-specific support to innovators and influence the innovation ecosystem

- There are programs in place, often through incubators and accelerators, that provide expertise on commercialising technologies. This can include providing expertise on IP, regulatory processes and business development. However, stakeholders said these supports do not always understand the AMR context, which can limit the extent of nuanced support they can provide.
- Stakeholders feel there is a lack of AMR 'superstars' in Australia who have had multiple successes in commercialising AMR solutions. Stakeholders frequently said that this sort of expertise would be very valuable to draw on, but this kind of expertise is not visible to most and / or isn't accessible.
- Contributing to this lack of expertise is a small and shrinking pool of AMR experts in Australia[1], and a growing risk of a significant knowledge gap emerging.
  - The pool of AMR experts doesn't match the significance of the problem they are trying to address. For example, worldwide, there are approximately 46,000 cancer researchers, 5,000 HIV/AIDS researchers and 3,000 AMR researchers.
  - The total number of authors on AMR publications halved between 1995 (3,599 authors) to 2020 (1,827 authors) and there was also an overall decline in publications
  - Research on this issue attributes this problem to a broken market for antimicrobials; private and public investment redirected to other areas, pharmaceutical companies shrinking their efforts in this space (largely due to lack of market incentives), and job changes and retirements of AMR experts.

"There are a lot of idiosyncrasies about AMR development that are different from other drugs…losing all that collective knowledge means that people are going to be traversing all the same pitfalls that people had found out about 50 years ago." – Innovation ecosystem stakeholder

"There is very patchy expertise in Australian universities and where it exists it can be very hard to find." - Developer of an AMR solution

"We now have a generational gap (in AMR expertise), and there's a risk of information and knowledge being lost if it's not carried on." – Innovation ecosystem stakeholder

[We need] a more mature R&D culture and more people who have taken drugs to market - it takes a lot of energy to find these experts and 'educate the sector'." – Developer of an AMR solution

"Australia doesn't have a critical mass of people who have commercialised products many times where most have only gone through commercialisation journey one or two times. It helps to have someone experienced providing advice." – Developer of an AMR solution

[1] United against Antimicrobial Resistance (2024), *Leaving the Lab: Tracking the Decline in AMR R&D Professionals*

Networks and supporting environment

There are mixed views on the support network environment for AMR, though all stakeholders feel that coordination is critical to the success of AMR solutions and the minimising AMR mission more broadly.

There were contrasting perspectives on the presence of AMR networks and/or the supporting environment for commercialisation

- Most stakeholders felt that there is opportunity for more collaboration and support – particularly across different stakeholder cohorts (academia, financial supports, businesses, etc.). For example:
  - Collaboration between university researchers and industry is limited
  - It is challenging to transition IP out of universities to pursue a commercial pathway
  - Clinical settings are not conducive to supporting research translation. Time and space is rarely carved out to allow clinicians to focus on research and development of solutions outside of their 'day job.'
- Some stakeholders felt that there were sufficient networks and opportunities for collaboration.

The scale and scope of the problem necessitates a coordinated and focused approach to developing solutions, which is currently limited.

- The World Health Organisation (WHO) describes AMR as "a complex problem that requires both sector-specific actions in the human health, food production, animal and environmental sectors, and a coordinated approach across these sectors."
- Many stakeholders feel that a more coordinated approach to combatting AMR in Australia is required. However, there are limited incentives for organisations or individuals to invest time, money and effort into developing an environment / ecosystem that facilitates collaboration.

"It is a serious problem and needs all angles, for example small molecules, vaccines, phages, etc. There is a lot of enthusiasm, but this needs funding and good coordination to crystallise results to develop AMR solutions. It's a great opportunity for academia and industry to work together." – Developer of an AMR solution

"There isn't an effective global mechanism to incentivise organisations or nations to focus on this. UK does it a bit, but its effectiveness is lessened if the rest of the world doesn't play ball" – Innovation ecosystem stakeholder

"There is a need for a co-ordinated approach. There are limited resources and importantly we need expertise in the area. Tapping into the international scene is vital and Australia is starting to do that." – Developer of an AMR solution

"From my perspective, there are opportunities out there if people want to take advantage of them. So certainly, from where I'm sitting it's not a huge gap." – AMR expert

Access to infrastructure

There are limited options in Australia for infrastructure – including laboratories, manufacturing, and other equipment and machinery – that some organisations need to develop their AMR solutions. There is also a general lack of collaboration and usage of the resources that already exist.

Infrastructure with limited or no options available in Australia.

Some AMR solutions, including those that are working with complex biological material or developing novel medical devices looking to scale, require infrastructure that isn't currently available in Australia. Examples of infrastructure with limited or no options in Australia for some AMR solutions include:

- Infrastructure to test and verify the efficacy of new solutions
- Infrastructure to package live bacteria to regulatory standards
- Wet labs, especially at larger scales.

Challenges that limit the access to Australian infrastructure.

Where there is existing infrastructure in Australia that could be leveraged but stakeholders shared a sense that useful infrastructure is 'sitting idle'. There are challenges accessing this infrastructure, including:

- Limited visibility of available local options and resources that could assist in navigating them
- Barriers in accessing existing infrastructure – especially in universities. This can be because:
  - Innovative firms (including AMR solutions) do not have existing relationships with many 'owners' of relevant infrastructure, and developing those relationships can be difficult
  - Access can be restricted and only available for academic reasons or to those associated with the university
  - Accessing this infrastructure can be too expensive.
- Some facilities and laboratories do not maintain valid certifications.

Implications

- Some AMR solutions – especially solutions looking to scale – may need to seek international options to progress through their commercialisation pathway.
- AMR solutions may need to build infrastructure themselves, which is an option that is too costly for some organisations to consider
- The lack of existing infrastructure and the mechanisms to develop new infrastructure will impact the efficacy of responding to future problems.

"We're well-funded in terms of research but can't produce a later-stage commercial product until infrastructure is in place to build it." – Developer of an AMR solution

"Access to scale-up infrastructure and support is very scarce in Australia for products/solutions that require wet labs/production." – Innovation ecosystem stakeholder

"While research is funded by them (government), they will not pay for infrastructure. We need to wait until big pharma builds the infrastructure." – Developer of AMR solution

"We have good infrastructure for research, testing, and trials nationally, supported by universities, large research organisations, and NATA-accredited testing facilities … The missing element is a database that lists all these resources, which could be very helpful." – Developer of an AMR solution

"Universities have equipment worth tens of millions sitting idle in multiple locations throughout Oz competing for work. we are too small a country for so many separate unis to be competing as they do." – Developer of an AMR solution

Regulatory systems

Existing regulatory systems do not adequately recognise the overarching AMR mission, which creates challenges for developers of AMR solutions to satisfy regulatory requirements.

Some AMR solutions have multiple applications which require multiple regulatory pathways

Some AMR solutions can cut across multiple sectors and respective regulatory bodies, meaning they may have to satisfy multiple regulatory requirements. For example, software that is intended to diagnose, prevent, monitor, treat, or alleviate a disease, injury or disability will:

- Be required to comply to with all medical device regulatory requirements.[1]
- Have more rigorous requirements regarding data handling, cyber security, and incident response processes due to the application in a clinical setting.

The regulatory environment is not suited to some innovative, particularly non-antibiotic, AMR approaches.

Some regulators may still see an 'antibiotic' as a necessary endpoint even though a non-antibiotic innovation may provide AMR-mitigating benefits. For example, an innovative and novel diagnostic test to help doctors identify appropriate antibiotic application would have significant AMR benefits but may not be recognised by regulators as an appropriate AMR endpoint.

This has been attributed to:

- Regulatory inflexibility, and the process for changing or advocating for change can be very time consuming.
- A lack of sufficient understanding of AMR, the context in which AMR impacts are felt, and/or the diverse avenues that it can be addressed.

These barriers and the requirements to overcome them contribute to the higher-than-typical scale of time for AMR solutions to reach commercialisation.

"For some AMR solutions, including our product, the validation activities necessary for regulatory compliance and commercialisation can be broken down into smaller milestones to mitigate project/commercial risks and manage costs." - Developer of an AMR solution

"We don't have time to first create standards for new technologies, and we shouldn't keep ignoring that the regulatory requirements that are in existence now could be part of the problem." – Developer of an AMR solution.

"The regulatory standards require test results in models designed for bacteriostatic or bactericidal approaches, or even single pathogens. This means that novel approaches get blocked by these regulatory standards. Examples include lack of flexibility in choice of clinical endpoints." – Developer of an AMR solution

"In our experience, non-antibiotic solutions get treated by regulators as if they should behave as antibiotics because they are treating or addressing bacterial or microbial conditions." – Developer of an AMR solution

[1]https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7380987/

Opportunities to support commercialisation of AMR solutions

Needs of researchers and SMEs commercialising AMR solutions

We have drawn from stakeholder consultation to capture the 'long list' of needs identified by researchers and SMEs commercialising AMR solutions.

Category	Needs	Category	Needs

Funding	• Dedicated AMR funding that:
	  • Acknowledges the overarching barriers to commercialisation and expects a different return on investment that goes beyond short-term financial returns
	  • Has a different approach to assessing investment opportunity for AMR (e.g. more AMR experts making decisions)
	• Provision of funding for clinical trials
	• Cross-disciplinary funding to solve for siloed funding approaches
		Infrastructure	• Improve visibility and access to existing infrastructure
			• Invest in infrastructure that is not available in Australia

Expertise and networks	• Solve for patchy expertise in Australia, and lack of visibility where it does exist
	• Facilitate a more mature AMR R&D culture through knowledge sharing
	• Continue and increase tapping into international AMR and commercialisation scene
	• Coordinated approach
	  • Cross-sector/discipline AMR supports
	  • Cross-sector/discipline collaboration
	  • Facilitate academia and industry collaboration
	• Improve understanding of the economic impacts of AMR
	• Increase government focus / support in these areas
		Regulatory and reimbursement	• Overhaul of regulatory system
			  • Development of acceptable regulatory standards
			  • Work with regulatory authorities to build understanding and improve regulatory pathway / standards
			  • An industry body that pushes regulatory change
			• Rapid regulatory review
			• Novel or different reimbursement models

Recommendations - revised

There is need to prioritise support for solutions combatting AMR by upgrading existing support structures and making a strong value-based case for public and private investment

An overarching question of this project was to identify if there was a need for an AMR specific accelerator or incubator, or more generally, AMR specific supports. While a gap analysis of supports available for commercialising AMR solutions was out of scope for this project, we have identified a clear need for government to prioritise and support the fight against AMR to address the overarching barriers to commercialisation and adequately respond to the scale and scope of the problem.

1 Increase awareness of the size, significance and relevance of AMR.

Improve understanding of the impact of AMR, the size of the problem, the scope of solutions, and the direct and indirect benefits of investing in developing AMR solutions, by:

a) Engaging with government and other stakeholders to clearly communicate the potential impact of AMR, barriers to developing AMR solutions and the need to invest in AMR, including by linking it to existing government priorities.
b) Identifying and engaging with researchers / SMEs with a potential role in AMR to explore opportunities for advancing AMR solutions, including by connecting them with AMR networks and peers to foster information-sharing and collaboration.

2 Develop a strategic roadmap to prioritise and address AMR through coordinated investment and action.

1. Develop a strategic business case advocating for investment in and prioritisation of AMR in Australia. This case should:
   a) Provide an outline of high- and low-benefit scenarios, including direct and indirect impacts of AMR on Australia, with links to current government priorities.
   b) Assess regulatory challenges, proposing mechanisms to streamline and coordinate regulatory processes to facilitate AMR commercialisation.
   c) Evaluate existing supports, identifying high-impact investment opportunities, potentially including an accelerator or incubator model. Consider ROI considering the broader ecosystem's capacity for finance, talent, and market access.
   d) Recommend roles for sectors, organisations, and individuals, emphasising the need for cross-sector coordination among researchers and industry to drive AMR solutions.
   e) Identify funding opportunities, including reallocating or enhancing existing support, as well as targeted AMR funding streams from domestic and international sources.

3 Consider additional low-cost initiatives to raise awareness of AMR and increase targeted support

1. CSIRO could pursue low-cost initiatives in parallel with recommendations 1 and 2, such as:
   a) Provide vouchers to travel internationally to access infrastructure unavailable in Australia.
   b) Where there is insufficient scale to develop solutions in Australia, identify opportunities for organisations to collaborate internationally, especially where and when the research and commercialisation pathways are stronger (ensuring return on research investment benefits are not exported from Australia); or where other funding sources are available e.g., international aid (such as Bill and Melinda Gates Foundation)
   c) Provide financial incentives for existing investment funds (e.g., MRFF) to invest in AMR as lower return investment.
   d) Strengthen pharmaceutical industry investment attraction efforts and seek stronger investment linkages with pharmaceutical industry.
   e) Tackle the long-known problem of improving access to infrastructure in universities e.g., by establishing a 'database' of research infrastructure.

Appendix 1: Conceptual framework

Approach to framework development

We developed a conceptual framework which guided our initial thinking and consultation around barriers to commercialisation. We captured the key characteristics that influence the needs, barriers, supports and gaps in the commercialisation of AMR solutions.

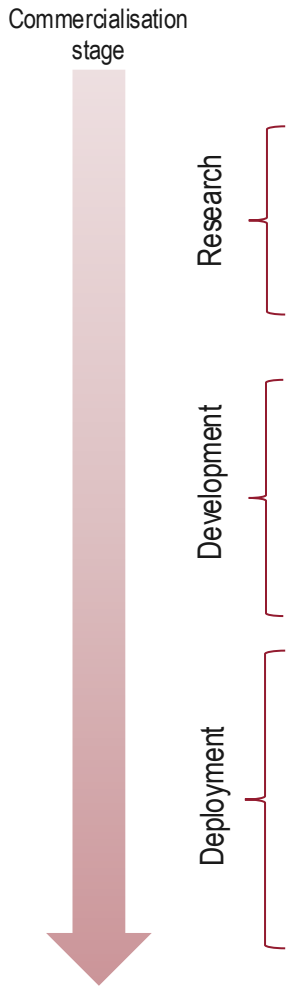
Characteristic	Why it's important
Commercialisation stage	The stage of commercialisation of a product / solution heavily influences the barriers to commercialisation it faces, and therefore the relevant needs and supports available. For example, funding during the commercialisation 'valley of death' where there is a significant increase in costs and risk is a common barrier.
Sector / solution type	The commercialisation journey, and therefore the different barriers and supports available, varies depending on the sector / solution type. For example, the requirements to commercialise a pharmaceutical product are much more involved and intensive than those for a software product. This comes with varying challenges and opportunities.
Organisation type*	The organisation type influences the supporting environment for commercialisation and therefore influences the supports and barriers. For example, a researcher in a university seeking to commercialise a new medical device will likely have more access to clinical trials expertise than a SME would.

We then sought to capture the needs, barriers, and effectiveness of supports available for these organisations through the lens of these characteristics

*Note, organisation type did not come through as a strong feature in our consultation.

Elements of the framework - commercialisation stage

We used Technology Readiness Levels (TRLs) to define each commercialisation stage. TRLs are used globally across a range of industries, sectors, and government.



TRL	Definition
TRL 1	Basic research
TRL 2	Applied research
TRL 3	Critical function or proof of concept established
TRL 4	Lab test / validation of alpha prototype component / process
TRL 5	Laboratory testing of integrated / semi-integrated system
TRL 6	Prototype system verified
TRL 7	Integrated pilot system demonstrated
TRL 8	System incorporated in commercial design
TRL 9	System proven and ready for full commercialisation deployment
Scale up 1*	Commercial scale up

*We have chosen to include an additional level – Scale up 1 – to capture scale up of a product / solution

Elements of the framework - solution type

We captured and categorised the major solution types for AMR-related products and services.

Solution type	Definition	Types of products / services (not exhaustive)
Materials	Barriers, coatings, and chemical disinfectants that provide direct benefits in terms of minimising AMR.	• Surface coatings • Impregnated fabrics • Packaging materials • Sanitisers, disinfectants and wipes
Pharmaceuticals	Synthetically- and biologically-derived drugs, to either treat or prevent AMR-related issues in humans or animals. The delivery or application of them may be considered under a separate solution type.	• Antimicrobial medicine • Nutritional supplements • Vaccines • Bacteriophage therapy
Medical devices / diagnostics	Instruments, apparatuses, machines, and other similar articles intended for use in diagnosis, prevention, monitoring, treatment, or alleviation of AMR-related issues, for private and/or clinical application. This does not include most software unless it has been developed as an indivisible component of a medical device/process.	• Wearable health monitor • Diagnostic imaging equipment • Implantable device
Envirotech	Engineering and technological devices and processes that address and minimise AMR risk in the broader environment. This does not include most software unless it has been developed as an intangible component of an Envirotech device/process.	• Water treatment systems • Air quality monitors
Software & AI	Digital solutions to support AMR-related activities in medical, professional, and/or personal contexts.	• Administration program that assists doctors in managing AMR-related issues • AMR Education app • AI-driven drug discovery and development software
Consulting & information services	Providing expert advice, data, and strategies to manage and mitigate the impact of AMR. This also includes policy advice in the AMR space.	• AMR risk assessment for medical • Educational / advocacy programs and workshops • Data, collection, analytics, and surveillance

Appendix 2: Project steering committee

Project steering committee members

CSIRO convened a steering committee for the project to inform framework development, identify stakeholders and test findings.

Stakeholder	Organisation
Susan Hawes	CSIRO
Sandra Roussel / Sarah Kosciuk	Department of Industry, Science and Resources
Thomas Ting	Department of Education
Sharath Sriram	RMIT University

Appendix 3: Barriers by solution type (from consultation)

Barriers to commercialisation – Pharmaceuticals

Pharmaceutical AMR solutions can face barriers across funding, skills, infrastructure and regulatory systems.

Barrier	Funding	Experts and networks	Infrastructure	Regulatory systems
What we heard	• Developing new antibiotics is costly and requires significant and complex biological testing. This necessitates the need for funding particularly in the early stages of clinical development. • Sustained funding through the later stages of development and commercialisation can also be difficult to secure. This is because pharmaceutical companies often require financial assurances to fund late-stage trials and commercialisation, but such incentives are rarely available. "For skilled groups, the support needed is largely financial. For unskilled people, they need access to the right expertise as well as the finance. It is really important to get the right expertise together with the right funding and the right intellectual property." – Pharmaceuticals company	• Experts in the AMR space are choosing to leave the field due to poor market dynamics, a lack of investment in the field, and complex regulatory systems to navigate. • This loss of valuable knowledge, experience and experience means there is less AMR-specific expertise that innovators can access. "And so having that expertise and knowledge and losing all that, that collective knowledge means that people are gonna be traversing all the same pitfalls that people had found out about 50 years ago." – Innovation ecosystem stakeholder	• Advanced infrastructure is required for the development of new pharmaceuticals, which is currently lacking in Australia. • Due to the constraints of infrastructure, many Australian pharmaceutical companies are forced to either: — Outsource critical testing phases to international facilities with required capabilities, or; — Establish in-house facilities which requires substantial financial investment and long wait times. "The verification and validation of innovative solutions are not only costly, but there is also limited infrastructure and testing lab availability in Australia for doing these tests.." – Medical devices / diagnostics SME	• Navigating the regulatory landscape to get AMR solutions approved can be complex and time-consuming. Pharmaceutical companies must comply with strict clinical and safety standards, adding to the complexity of these processes. • Pharmaceutical companies face many regulatory hurdles as proving efficacy and safety of new antibiotics can be complex and costly, especially for novel classes of antibiotics. "Therefore, the regulator might ask you to do trials and then fails you afterwards because you didn't meet the endpoints and there have been several biofilm companies or anti biofilm companies who have gone bust because of that regulatory issue." – Pharmaceuticals company

Barriers to commercialisation – Medical devices and diagnostics

Medical devices and diagnostics that focus on addressing AMR face barriers across funding, skills, infrastructure and regulatory systems, including as they look to scale which requires additional funding and infrastructure.

Barrier	Funding	Experts and networks	Infrastructure	Regulatory systems

What we heard	• Funding is a significant barrier to developing AMR-specific medical devices and diagnostics.
	• Lack of funding impacts the ability to conduct clinical trials, which are essential to demonstrating the safety and efficacy of medical devices and diagnostics.
	• It is challenging to secure partnerships or investments without clinical trials, as investors often require evidence of successful application before committing to funds. Establishing industry partnerships are especially crucial to small to medium-sized companies.
	
	"Funding. funding. funding. we are in medical devices and near impossible to raise capital here in Oz to progress through clinical ." – Medical devices / diagnostics company
		• Many experts in the AMR space are choosing to leave due poor market dynamics, a lack of investment in the field, and complex regulatory systems to navigate.
		• Loss of valuable knowledge and experience poses risks to commercialisation success in Australia because it limits access to expertise.
		
		"Many passionate AMR researchers are being forced to leave the field – draining invaluable knowledge, expertise, and dedication at the very moment when we need it most." – Medical devices / diagnostics company
			• There is a lack of specialised infrastructure and testing labs in Australia to develop medical devices and diagnostics. This results in:
			  • Smaller firms relying on partnerships with larger pharmaceutical companies that have access to facilities or the recourses to establish the relevant infrastructure.
			  • Outsourcing testing and development to international facilities in the absence of inadequate local infrastructure.
			• In addition, funding for R&D often does not account for the high costs associated with accessing or developing specialised infrastructure.
			
			"They will not pay [for] the infrastructure, they will not build the factories at the volumes that you need." – Medical device company
				• Many AMR solutions span various sectors (e.g. diagnostics, pharmaceuticals, and medical devices), each with distinct regulatory requirements.
				• The distinct regulatory requirements of different sectors means that one solution must go through different regulatory approval processes, costing time and money.
				• Regulators often lack a comprehensive understanding of AMR-specific solutions, leading to the absence of well-defined criteria or standards for evaluating these technologies. As these technologies are often novel and rapidly evolving, regulators may not have the expertise or resources needed to assess them effectively.
				
				"What we're doing is a combination product. So, it's probably - from a regulatory perspective - the most challenging product to bring to market." – Medical device company

Barriers to commercialisation – Software & AI

The barriers to commercialising software & AI products that are distinctive to AMR solutions manifest when the products intersect with other regulatory requirements.

Barrier	Funding	Experts and networks	Infrastructure	Regulatory systems

What we heard	• Obtaining funding for AMR-specific software and AI solutions can be difficult because:
	  • This is an emerging field with limited funding opportunities / streams specific to software and AI development.
	  • Determining whether a software application qualifies as a medical device can be complex and therefore funding may be hard to secure / justify in the healthcare sector.
		• There are fewer experts and researchers in the field, given:
		  • Developing high-tech software and AI is a new and upcoming field.
		  • There is a lack of understanding and knowledge around new technologies, in which investors may have limited familiarity with the capabilities and benefits of emerging technologies.
		  • There is general hesitancy around software and AI applications due to market and technical immaturity.
			• We did not hear any AMR specific barriers to infrastructure for software and AI.	• There is uncertainty surrounding the regulatory requirements for software and AI applications.
				• This is because:
				  • This is an emerging field with limited regulatory frameworks established.
				  • The technology is rapidly advancing at a faster pace than regulatory agencies.
				  • Regulators may lack the expertise necessary to evaluate these technologies effectively.
				  • AI applications often handle sensitive patient data, raising concerns about compliance with data protection regulations.

"At the time when we started (2015), there was a lack of knowledge and even resistance towards smartphone-based applications." - Software & AI company

Note: we did not receive any feedback from stakeholders in the materials, consulting and information services and envirotech sectors.

Appendix 4: Barriers by solution type and commercialisation stage (from desktop research)

General barriers by solution type and commercialisation phase

In addition to consultations, we have summarised the general barriers faced in commercialising AMR solutions drawn from desktop research.

Commercialisation stage

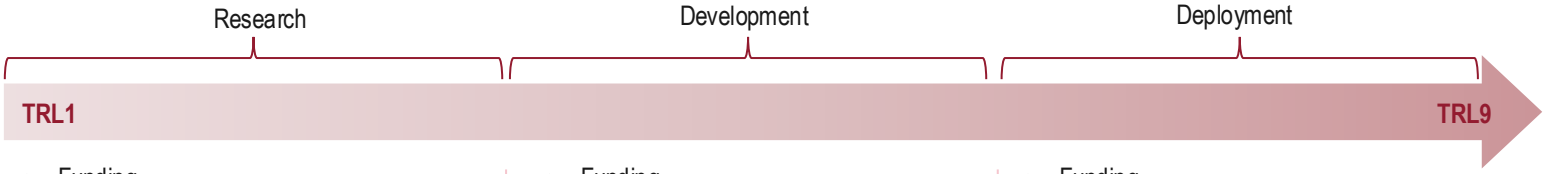
Solution type	Research (TRL1)	Development	Deployment (TRL9)
Pharmaceuticals	• Funding • Expertise • Grant writing demands • Research plan • Facilities / equipment • Drug / candidate discovery	• Funding • Expertise • Grant writing demands • Facilities / equipment • Pre-clinical studies partner • Study management • Manufacturing plan • Clinical trial site selection • Valley of death	• Funding • Expertise • Grant writing demands • Facilities / equipment • Study management • Clinical trial site selection / patient recruitment • Valley of death • Specific regulatory pathway (depending on location, domain and intended use) • Quality management and post-market monitoring
Medical devices / diagnostics	• Funding • Expertise • Grant writing demands • Research plan • Facilities / equipment • Clinician expertise	• Funding • Expertise • Grant writing demands • Facilities / equipment • Pre-clinical studies partner • Study management • Validation of value proposition • Manufacturing plan • Clinical trial site selection • Valley of death	• Funding • Expertise • Grant writing demands • Facilities / equipment • Study management • Clinical trial site selection / patient recruitment • Valley of death • Specific regulatory pathway (depending on location, domain and intended use) • Quality management and post-market monitoring

https://www.britishcouncil.id/sites/default/files/annex_2_technology_readiness_level_trl_033020_final.pdf
https://dmtc.com.au/wp-content/uploads/2019/04/DMTC-TRL-Guideline-MCM-2019.pdf
https://ris.utwente.nl/ws/portalfiles/portal/252322011/Developing_a_TRL_oriented_roadmap_for_the_adoption_of_biocomposite_materials_in_the_construction_industry.pdf
Digital Health in Australia – Opportunities and Challenges, Australian Market Entry, ANDHealth

General barriers by solution type and commercialisation phase

In addition to consultations, we have summarised the general barriers faced in commercialising AMR solutions drawn from desktop research.

Commercialisation stage



Solution type	Research	Development	Deployment
Materials[1]	• Funding • Expertise • Grant writing demands • Research plan • Customer / consumer discovery • Technical testing	• Funding • Expertise • Grant writing demands • Customer / consumer discovery • Validation of value proposition • Technical testing • Manufacturing process (including scaling) • Valley of death	• Funding • Expertise • Grant writing demands • Data handling • Customer / consumer trialing • Data sets • Technical testing • Sales and marketing • Large capital investment for manufacturing • Navigating intersecting regulatory requirements relevant to intended use case • Any additional data requirements necessary for AMR-related applications
ICT	• Funding • Expertise • Grant writing demands • Research plan • Customer / consumer discovery • Data sets and data handling • Technical testing	• Funding • Expertise • Grant writing demands • Data handling • Customer / consumer discovery • Validation of value proposition • Cyber security • Need to hire lots of people (front end, back end, developers) • Technical testing	• Funding • Expertise • Grant writing demands • Data handling • Technical testing • Customer / consumer trialing • Cyber security • Need to hire lots of people (front end, back end, developers) • Sales and marketing • Any additional data requirements necessary for AMR-related applications • Navigating intersecting regulatory requirements relevant to intended use case

https://www.britishcouncil.id/sites/default/files/annex_2_technology_readiness_level_trl_033020_final.pdf
https://dmtc.com.au/wp-content/uploads/2019/04/DMTC-TRL-Guideline-MCM-2019.pdf
https://ris.utwente.nl/ws/portalfiles/portal/252322011/Developing_a_TRL_oriented_roadmap_for_the_adoption_of_biocomposite_materials_in_the_construction_industry.pdf
Digital Health in Australia – Opportunities and Challenges, Australian Market Entry, ANDHealth