Australian Government
Department of Industry, Science and Resources

Australia's RNA Blueprint: Understanding our ribonucleic acid (RNA) potential

Australian Government response to stakeholder feedback

Our purpose is to help the government build a better future for all Australians through enabling a productive, resilient and sustainable economy, enriched by science and technology.

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The purpose of this publication is to describe potential actions that stakeholders – researchers, industry and government – could take to support development of Australia's RNA sector.

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Introduction

The Australian Government has committed to delivering a Future Made in Australia to boost investment and productivity, create jobs and seize the opportunities of a shifting global economy. This ambition will be built on the back of a strong, diverse and competitive Australian manufacturing industry that drives new economic investment and helps secure Australia's future prosperity. Medical manufacturing and biotechnologies (such as RNA technology) are areas where Australia has potential to develop an enduring comparative advantage, and where it is in our national interest to develop sovereign capability. These areas are specified as priorities in several aspects of our government's agenda, including the National Reconstruction Fund Corporation (NRFC), Australia's Economic Accelerator (AEA) and List of Critical Technologies in the National Interest.

RNA technologies are included in our Medical Science Co-investment Plan (CIP) published on 15 April 2024, which identifies an opportunity for Australia to focus on high-value, innovative, complex therapeutics (such as RNA medicines) and realise economic opportunity. The RNA sector can contribute to our industrial transformation and advanced manufacturing capability, ensure we are making more here in Australia, build skills for well-paid jobs and improve healthcare for all Australians.

The Department of Industry, Science and Resources (the department) heard during consultations in October 2023 that the potential of Australia's RNA sector is high, but that it is complex, interdependent and complementary to other medical biotechnologies. Stakeholders highlighted that efforts to develop this sector require a more nationally coordinated approach.

While this blueprint leverages existing initiatives to grow the RNA sector, stakeholders and the Medical Science CIP highlighted that many of its challenges and opportunities are similar to those in the broader medical biotechnology sector. Successful implementation of actions to support RNA sector growth will likely have flow-on benefits to our broader medical science priority area.

Why RNA science and technologies?

Ribonucleic acid, or RNA, is essential to all living organisms and carries genetic information from the nucleus (in the form of deoxyribonucleic acid, or DNA) to ribosomes where proteins are made. RNA technology rose to global prominence in 2020 with messenger RNA (mRNA) vaccines playing a critical role in the COVID-19 pandemic response. RNA's involvement in normal cell function is key to unlocking its therapeutic possibilities – vaccine, therapeutic, diagnostic or biosensor – and application to human and animal health. These applications are summarised in Appendix A – RNA technologies and use.

Globally, over 200 human RNA medicines (therapeutics and vaccines) are under development.[1] The size of the global RNA technology market – estimated to be between USD$46–107 billion by 2030[2] – highlights the potential value in developing end-to-end RNA manufacturing capability. It has been estimated that Australia's RNA sector could add up to $8 billion to Australia's gross domestic product over the 10 years to 2033.[3]

RNA technology is at the forefront of a therapeutic revolution given its immunogenicity, capacity for rapid development – an RNA sequence can be altered to adapt to an evolving pathogen or for personalised treatment – and safe administration, when compared to conventional platforms such as small molecules and proteins. Ongoing RNA delivery system development will enable effective and targeted tissue or cell specific

[1] Chemical Abstracts Service (2022) *RNA-Derived Medicines: A Review of the Research Trends and Developments* (American Chemical Society).
[2] Grandview Research (2020) mRNA Therapeutics Market Size <https://www.grandviewresearch.com/industry-analysis/mrna-therapeutics-market-report> Accessed 12 July 2023; Precedence Research (2023) mRNA Therapeutics Market – Global Industry Analysis, Size, Share, Growth, Trends, Regional Outlook, and Forecast 2023–2032 <https://www.precedenceresearch.com/mrna-therapeutics-market> Accessed 12 June 2023.
[3] Deloitte (2023) *RNA Sector advice* (unpublished).

RNA delivery to achieve desired biological effects.

Realising the potential of RNA medicines will improve the standard of care for many diseases, treat previously untreatable diseases, enable tailored personalised medicine and boost biosecurity capability to address key animal diseases that threaten Australia's livestock industry and domestic food security.

Australia's RNA opportunity

There are significant opportunities for Australia to capitalise on our existing strengths and become a leading regional participant in RNA medicines – both development and manufacturing. Australia's focus should be where our strengths (Table 1) and global development opportunities overlap.

Table 1: Australia's current RNA and clinical/animal health strengths

Current RNA strengths	Key clinical/animal health capability
Fundamental and RNA science	Cancer, including melanoma
mRNA therapeutics and vaccines for human and animal health	Tropical and zoonotic diseases (especially infectious diseases)
circular RNA (circRNA)	Rare diseases
RNA therapeutics (including antisense oligonucleotides (ASO))	Neurological and cardiac diseases
RNA biomarkers and RNA diagnostics	
non-coding RNA (including long non-coding RNA and small interfering RNA (siRNA))	
Lipid nanoparticle (LNP) delivery systems and next generation nanotechnology delivery systems	

We must also be prepared to pivot – with the arrival of new RNA technologies or health risks – to seize future opportunities as they arise. This includes addressing shared health concerns, responding to emergencies, especially in the Asia-Pacific region, and changing geo-strategic and market conditions.

Australia is an attractive investment location due to our:

- clinical trials strengths, including an excellent first in human clinical trials sector and strong financial support though the government's Research and Development Tax Incentive (R&DTI) Clinical Trials Determination (see https://www.legislation.gov.au/F2022N00078/latest/text)
- clinical and research strengths
- specific grant programs and collaborative networks between industry, academia and government
- significant investments in establishing the foundational components of a thriving RNA ecosystem (Figure 1)
- manufacturing capability
- workforce training programs
- stable socioeconomic environment
- strong intellectual property (IP) regime.[4]

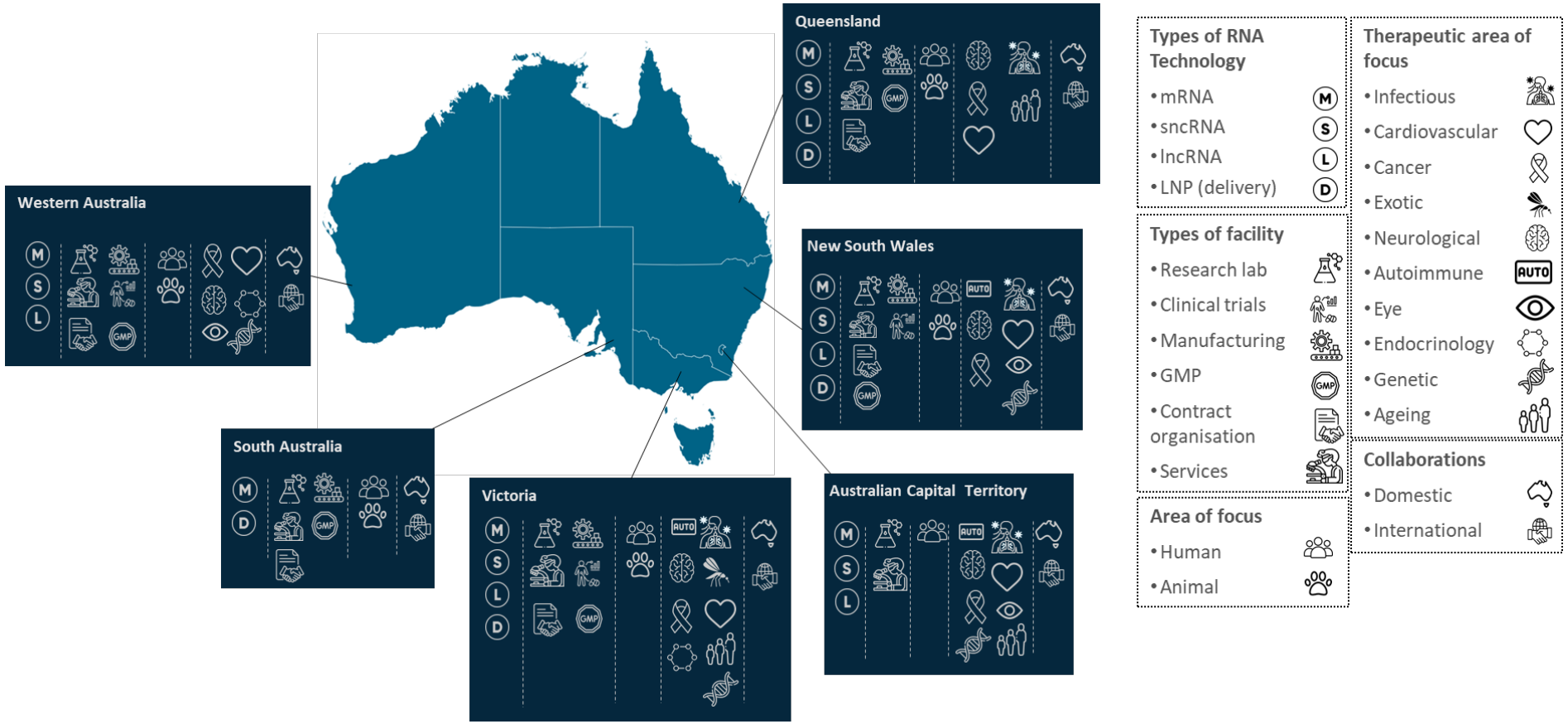
[4] Australian Academy of Science (2022) *RNA Science Report* (unpublished).

There is already considerable support provided for the RNA sector in Australia (Appendix B) including government/private provided research funding, the R&DTI, translational infrastructure, industry-led RNA translation and commercialisation centres, and RNA and Good Manufacturing Practice (GMP) skills initiatives. Major Australian Government programs – the $392.4 million Industry Growth Program (IGP), the $15 billion NRF and the $1.6 billion AEA – have medical science and manufacturing, as a priority. These programs are established and will support a pipeline of potential RNA projects through translation, commercialisation and manufacturing.

The government's Future Made in Australia agenda will put in place the structures and enablers to facilitate greater investment attraction and potentially drive the next wave of pioneering medical science projects that create jobs and drive economic growth. These reforms will also help Australia compete for international investment. A Future Made in Australia is about giving Australian industry every possibility to fully share in the reward of our future prosperity – including arming them with science and technology to underpin it. The Government is providing $5.1 billion funding over 35 years from 2023–24 for investments in innovation, science and digital capabilities to support a Future Made in Australia, including $595 million over 5 years from 2023–24. These technologies will have direct and indirect flow on effects to support Australia's RNA capability.

Multinational RNA healthcare companies – Moderna, BioNTech and Sanofi – as well as clinical stage companies (for example Myeloid Therapeutics) and contract development and manufacturing organisations (for example Bridgewest Australia Holdings (BioCina)), have all invested here and have indicated they want to be part of further developing Australia's RNA manufacturing and clinical trial capabilities.

Figure 1: Overview of Australia's RNA capabilities[5]



[5] Source: Department of Industry, Science and Resources analysis of publicly available data

Notes: Types of RNA Technology grouped

- M= mRNA
- S= short noncoding RNA (family includes micro RNA, small interfering RNA, double stranded RNA, antisense RNA, guide RNA)
- L= long noncoding RNA (family includes lncRNA, antisense RNA, RNA aptamers)
- D=Lipid nanoparticles and delivery technologies. (*RNA Science Report* (AAS, 2022)).

- Capability data detail is based on 95 entity data as at 8 September 2023.
- Strong RNA capabilities shown only, incidental RNA capabilities not shown. All data will be reviewed with other evidence and these may be updated as required.

Selection of existing measures across the Australian RNA Sector

Investment

Australian Government

Industry Investment

$15 billion ***National Reconstruction Fund (NRF)*** (NRF priorities - $1.5 billion for medical manufacturing; $1 billion for critical technologies, including biotechnologies)

$392.4 million ***Industry Growth Program*** to support SME commercialisation & growth in NRF priority areas

$1.6 billion ***Australia's Economic Accelerator*** to support University translation & commercialisation in NRF priority areas

Moderna Partnership

Research Investment (figures at industry sector level)

Medical Research Future Fund & Medical Research Endowment Account (more than $1.5 billion each year combined)

R&D Tax Incentive (FY2021-22 – about $900 million in R&D expenditure claimed)

Other research funding initiatives (e.g. ARC, CRC) (more than $1 billion each year combined)

State Government

NSW

R&D initiatives over 10 years ($119 million)

NSW Pilot Facility ($96 million total investment)

VIC

mRNA Victoria Research Acceleration Fund ($27 million over two rounds)

Moderna Partnership

QLD

Translational Science Hub co-investment

Advance Queensland's Science into Industry Co-Investment Scheme

SA

BioCina mRNA Centre of Excellence co-investment

Research and Innovation Fund

WA

Future Health Research and Innovation Fund

Research, Translation and Infrastructure

Industry Initiatives and Infrastructure

BioCina

Centre of Excellence and mRNA manufacturing (with partners Cytiva & University of Adelaide)

BioNTech

mRNA Facility at La Trobe University and Innovation Centre at Parkville

Moderna

Moderna Regional Research Centre for Respiratory Medicines and Tropical Diseases, Monash-Moderna Quantitative Pharmacology Accelerator and mRNA Platform Incubator Network

Myeloid Therapeutics

Operation of the NSW Pilot Facility

Sanofi

Translational Science Hub (with partners University of Queensland & Griffith University)

National Collaborative Research Infrastructure

Therapeutic Innovation Australia, including RNA Products

Bioplatforms Australia

Phenomics Australia

National Imaging Facility

Population Health Research Network

Institutional Infrastructure

BASE mRNA facility (University of Queensland)

UNSW RNA Institute & RNA Production and Research Network

NSW RNA Research and Pilot Manufacturing Facility (Macquarie University, NSW)

Australian Centre for RNA Therapeutics in Cancer (University of Western Australia)

Clinical trials infrastructure (national)

Accelerators and Incubators (national)

Skills and Training

Monash Centre for Advanced mRNA Medicines Manufacturing and Workforce Training (VIC)

The University of Technology Sydney's (UTS) Biologics Innovation Facility

Queensland BioManufacturing Alliance

The NSW Government GMP Future Workforce Roundtable

NSW RNA Future Leaders Program

Industry Doctoral Training programs

The blueprint

Understanding our RNA potential

Goals	Possible stakeholder actions
1. Connect and promote our National RNA ecosystem	Build an RNA Growth Leadership Initiative Identify opportunities to increase awareness of RNA technologies
2. Increase skills and access to infrastructure	Publish a capability network index to support collaboration and infrastructure access Connect and promote existing skills training initiatives for workforce development Workforce assessment and planning Build the skilled workforce
3. Improve research, translation and investment	Leverage and promote resources on commercialisation of RNA technologies, including developing IP landscape and product development reports for the RNA sector Ensure the ongoing development of the RNA technology pipeline
4. Lead RNA regulation and guidance development	Australia continues to be an agile, influential leader in RNA regulatory science
5. Build and strengthen international partnerships	Support international RNA research and regulatory science collaborations

This blueprint draws on what we heard from stakeholders. Stakeholders were clear that Australia has broader opportunities in the advanced therapeutics space beyond RNA, and the Australian Government is committed to continuing the conversation on growing our broader medical biotechnology sector.

This blueprint focuses on Australia's national RNA sector, leveraging our strong research capabilities and considerable existing government and private investment into infrastructure and other initiatives. There is already support for the sector, including:

- government provided research funding (for example, the Medical Research Future Fund, Australian Research Council, state government programs)
- the R&DTI
- translational infrastructure delivered by National Collaborative Research Infrastructure Strategy infrastructure projects, academia and biomedical precincts
- industry-led RNA translation and commercialisation centres.

Industry and academia are delivering a number of initiatives to support RNA and GMP skills development. Major Australian Government programs – the IGP, NRF and AEA – have been established and will support a pipeline of potential projects through translation, commercialisation and manufacturing.

The consultation process itself has realised immediate benefits to the sector. Industry, academia and TGA are discussing RNA platform regulatory guidance for therapeutic goods, and stakeholders have a clearer view of the sector's participants. Industry and academia are collaborating and are encouraged to continue this to grow Australia's RNA sector.

The department has identified the following areas and actions that governments, academia and industry could collectively address to supercharge the growth of Australia's RNA sector.

Goals

1. Connect and promote our national RNA ecosystem

Australia has a nascent RNA sector concentrated in a number of hubs comprised of researchers, key infrastructure and industry capability. Connecting and promoting our RNA sector nationally will realise growth opportunities; ensure there is coordinated government and industry investment along the entire ecosystem and value chain; and maintain public support.

2. Increase skills and access to infrastructure

The success of Australia's RNA Sector, and its ability to attract investment and collaboration, is highly dependent on the pipeline of skilled human capital at all levels as well as its infrastructure, products and services.

3. Improve research, translation and investment

Australia is recognised for its strength and expertise in RNA science and disease research but needs to increase the success of research translation, to retain value onshore and position itself as the "go to" global investment destination.

4. Lead RNA regulation and guidance development

Regulatory planning is critical to both researchers and commercial developers. Regulatory guidance for mRNA platform products is still evolving; other RNA technology platforms are yet to be realised. Australia has an opportunity for industry-regulator cooperation, taking a One Health approach, to lead on the development of clear RNA platform regulatory guidance to improve RNA medicine access for human and animal disease prevention and treatment.

5. Build and strengthen international partnerships

The RNA sector is global. A thriving Australian RNA ecosystem requires active international collaboration. By working with international partners, Australia can boost business opportunities, build research partnerships (addressing priority diseases and emergent threats) and promote harmonised regulatory approaches to improve market access opportunities for Australian produced RNA medicines.

Potential actions

Australia's RNA sector needs a coordinated and collaborative effort across the Australian Government, states, industry and academia, as well as close engagement with the community, for it to flourish. The actions described below seek to address the areas identified above, and will require all parts of Australia's RNA sector to contribute. They complement and leverage (but avoid overlapping with) existing policies, programs and investments to supercharge Australia's RNA sector growth. These are summarised below. Further details are in Appendix B – Existing policy, programs and investment.

1. Connect and promote our national RNA ecosystem

Under this action, the RNA sector could:

1.1 Build an RNA Growth Leadership Initiative

The RNA sector could join together to establish an RNA Growth Leadership Initiative to advance the development of RNA technologies, with an emphasis on building and connecting Australia's capabilities across the entire value chain. A whole of value chain approach is crucial if Australia is to maximise the return on its research investments and encourage industry to grow high value medical manufacturing and jobs in Australia.

The Initiative could engage with Australia's Cell and Gene Catalyst to address mutual areas of interest such as skills development, knowledge sharing and building Australian capability across the entire value chain, from research and development (R&D) to manufacturing, clinical trials and commercialisation.

To help coordinate and drive this initiative, the department will convene an RNA Working Group with membership drawn from academia, industry, peak bodies and governments via an open expression of interest process; all participants must be actively working in the RNA ecosystem and all jurisdictions will be represented.

The RNA Working Group would build upon existing connections to grow our RNA sector. It could achieve this by:

- providing advice to support collaboration and to promote research, translation, commercialisation to develop a product pipeline
- promoting mobility between industry and research participants to build skills and connections

- advising on capability gaps and activities to develop and support a skilled workforce.

1.2 Identify opportunities to increase awareness of RNA technologies

Stakeholders could collaborate to improve public awareness of RNA technologies and medicines, including health benefits, and to showcase the diverse employment opportunities across the sector. The government's response to science and education reviews including, but not limited to, the Pathway to Diversity in STEM Review and Unleashing the Potential of our Health Workforce (Scope of Practice Review),[6] may provide opportunities to highlight career pathways and the medical benefits arising from advanced therapeutics, such as RNA medicines.

2. Increase skills and access to infrastructure

Existing initiatives

The Australian Government, states, industry and academia have already undertaken steps to support a more effective education and training system that will address skills along the entire RNA value chain. Investing in people is key to the Government's Future Made in Australia plan. The complementary Jobs and Skills Australia (JSA) and Jobs and Skills Councils (JSC) work together to identify and meet future workforce needs, while also providing industry with a stronger voice to deliver the best outcomes for learners and employers.

Other interventions are being driven by the Employment White Paper, the Universities Accord Review of Australia's Higher Education System (the Accord) and the National Skills Agreement and Migration Strategy. The government's response to the Pathway to Diversity in STEM Review provides an opportunity to consider how to support greater inclusion in the STEM sector and encourage interest in the RNA (and broader medical biotechnology) sector. The 2024–25 Budget provides $38.2 million over 8 years to support diversity in STEM. The Department of Health and Aged Care's independent audit of Australia's health and medical research workforce will amongst, other things, identify capability strengths and gaps, and available training and professional development[7] to inform further opportunity. These government led initiatives are complemented by a number of state government, industry or University RNA and/or GMP skills initiatives.

Under this action, stakeholders could:

2.1 Publish a capability network index to support collaboration and infrastructure access

To facilitate collaborations in the ecosystem, a searchable RNA capability network index covering major organisations in the RNA ecosystem, their capabilities and infrastructure could be published on the department's website. The searchable index could:

- assist sector participants to identify prospective partners
- support collaboration on a national basis to meet business needs.

2.2 Connect and promote existing skills training initiatives for workforce development

Discussions can be facilitated with existing training and higher education programs and initiatives along the RNA sector value chain to encourage collaboration and fit for purpose training activities, avoiding unnecessary duplication and gaps.

[6] Department of Health and Aged Care, 2023.
[7] Govt to scope health and medical research workforce, InnovationAus.com (6 February 2024).

2.3 Workforce assessment and planning

A national RNA workforce assessment and planning exercise could be conducted (and repeated as required) in collaboration with stakeholders, including industry, academia and regulatory agencies. This work would underpin our understanding of the sector's workforce structure, alignment with the existing education and training system, and gap identification.

Periodic workforce assessment and planning is a necessary action to improve, target and support training programs at VET/University levels or to support skills development through alternate mechanisms such as industrial fellowships. The insights and forecasts provided would:

- ensure the training sector is data-driven, understands barriers and opportunities, and is able to respond to evolving workforce demand
- assist governments to determine the strengths and weaknesses of the domestic workforce
- ensure adjacent skills and stakeholder activities are considered as part of workforce strategy where there is a common interest.

2.4 Build the skilled workforce

Using the workforce assessment and planning insights and forecasts, governments and stakeholders could develop strategies to meet the sector's needs. Piloting these strategies through existing government or industry programs could be explored.

3. Improve research, translation and investment

Existing initiatives

We will continue to support RNA R&D including through the National Collaborative Research Infrastructure Strategy, competitive grant or funding programs, the R&DTI which encourages R&D investment and, since the introduction of the R&DTI Clinical Trials Determination in April 2022, over 200 companies have relied upon it to support clinical trials outcomes,[8] and incubator and accelerator programs. Universities would be encouraged to use the Higher Education Research Commercialisation (HERC) IP Framework to support universities and businesses/industry to work on research and commercial projects.

Strengthening Australia's R&D ecosystem and harnessing the contribution of science is vital to a Future Made in Australia. The Australian Government invested over $12 billion in R&D in 2023–24. To maximise return on investment in R&D, the government announced a strategic examination of Australia's R&D system in the 2024–25 Budget.

The Australian Government's $15 billion NRF will also support, diversify and transform Australian industry in government-identified priority areas of the Australian economy, including medical science and enabling technologies including biotechnology, AI, quantum and robotics, all of which are relevant to the RNA sector. A pipeline of RNA technologies and companies for potential future NRF Corporation investment can be grown through two Australian Government initiatives that support the government identified priority areas – the $392.4 million IGP and the $1.6 billion AEA. The IGP provides support to innovative start-ups and small and medium enterprises in priority areas, including medical science, to commercialise ideas and grow their businesses through advice and matched grant funding. The AEA supports the translation and commercialisation of university research.

[8] Provided 17 February 2024 by Research & Development Tax Incentive Branch, Department of Industry, Sciences and Resources (unpublished).

Under this action, stakeholders could:

3.1 Leverage and promote resources on commercialisation of RNA technologies, including developing IP landscape and product development reports for the RNA sector

Research sector support could be enhanced by promoting existing, high-quality translation and commercialisation advice, and developing RNA translation specific resources, including IP resources and product development tools. These could be targeted at university research translational offices to improve their capability to support academia to successfully progress proof of concept and research translation.

The intent of this action is to incentivise universities to align their RNA IP policies to overcome current incompatibilities.[9] Standardised RNA IP policies support IP negotiations and formation of industry-university partnerships, especially multi-university arrangements. Expediting the negotiation process will be critical to progress Australia's strength in research in a competitive RNA technology environment.

3.2 Ensure the ongoing development of the RNA technology pipeline

Research is core to developing innovative and emerging technologies such as RNA technology. Biological based technologies have long commercialisation times, with a 10- to 15-year horizon for RNA medicines reported. Actions that could be taken would seek to support the pipeline of RNA technologies/medicines and companies for potential future investment through the AEA, IGP, NRF and other programs.

Additionally, through the upcoming revitalisation of Australia's National Science and Research Priorities and release of the Accord, opportunities for further research efforts, using RNA and adjacent technologies, to address challenges and drive human and animal health innovation will be explored.

The strategic examination of Australia's research and development system announced in the 2024–25 Budget will also consider ways to maximise the value from investment in R&D.

Opportunities to encourage or promote RNA research translation in Australian Government competitive grant or funding programs can be pursued.

The CRC-P grants program supports government priorities including the priority areas. The program provides funding of up to $3 million for business-research collaborations with a small to medium enterprise lead, on projects which solve industry identified challenges. Now in its 9th year, the CRC Projects program has committed $553 million to establish 253 CRC-Ps, leveraging $1.144 billion in cash and in-kind support. A staged approach to CRC-P options could include:

- encouraging industry-led RNA collaborative research project collaborations in the coming round/s
- within the next two years, including nucleic acid medicine projects (including technology and carrier development) as a priority within round/s
- within the next five years, including RNA medicine projects (including technology and carrier development) as a priority within rounds.

[9] Australian Academy of Technological Sciences & Engineering (June 2022) *mRNA Research Report* (unpublished), p 24.

A staged approach signals to industry and academia the value of collaboration, allowing them opportunity to find and make those collaborative RNA research arrangements; supports improved translation development by bringing in industry engagement early, helping to pull through the ideas; and supports skills development. Under these options, the relevant rounds would still be open to all other areas.

4. Lead RNA regulation and guidance development

RNA medicines have emerged as a developing strategic technology for human and animal disease prevention and treatment. As a platform technology, it should simplify product development and regulatory review. Various product development steps will be remarkably similar across mRNA medicines from the same manufacturer – such as parts of the mRNA, LNP, manufacturing methods and analytical techniques. Onshore RNA manufacturing provides a new co-regulatory opportunity for regulators and locally based manufacturers to develop regulatory guidance and standards, assisting the assessment of RNA medicines and domestic innovation capability, while maintaining safety, quality and efficacy. Regulatory speed while maintaining strict quality standards can provide Australia with a comparative advantage, making it a destination for global research and investment.

Under this action, stakeholders could:

- continue to build regulatory capabilities, and contribute to the development of regulatory science regionally and internationally
- promote international collaboration and/or alignment, improving international market access for Australian manufactured RNA medicines.

All parties – Australian regulators (TGA, OGTR, APVMA), industry and academia (including the research/industry working group already established to support RNA platform guidance) – could act, and collaborate where possible, to continue to ensure Australia's regulatory system is modern and responsive to accommodate emerging technologies, including RNA medicines.

5. Build and strengthen international partnerships

Under this action, stakeholders could:

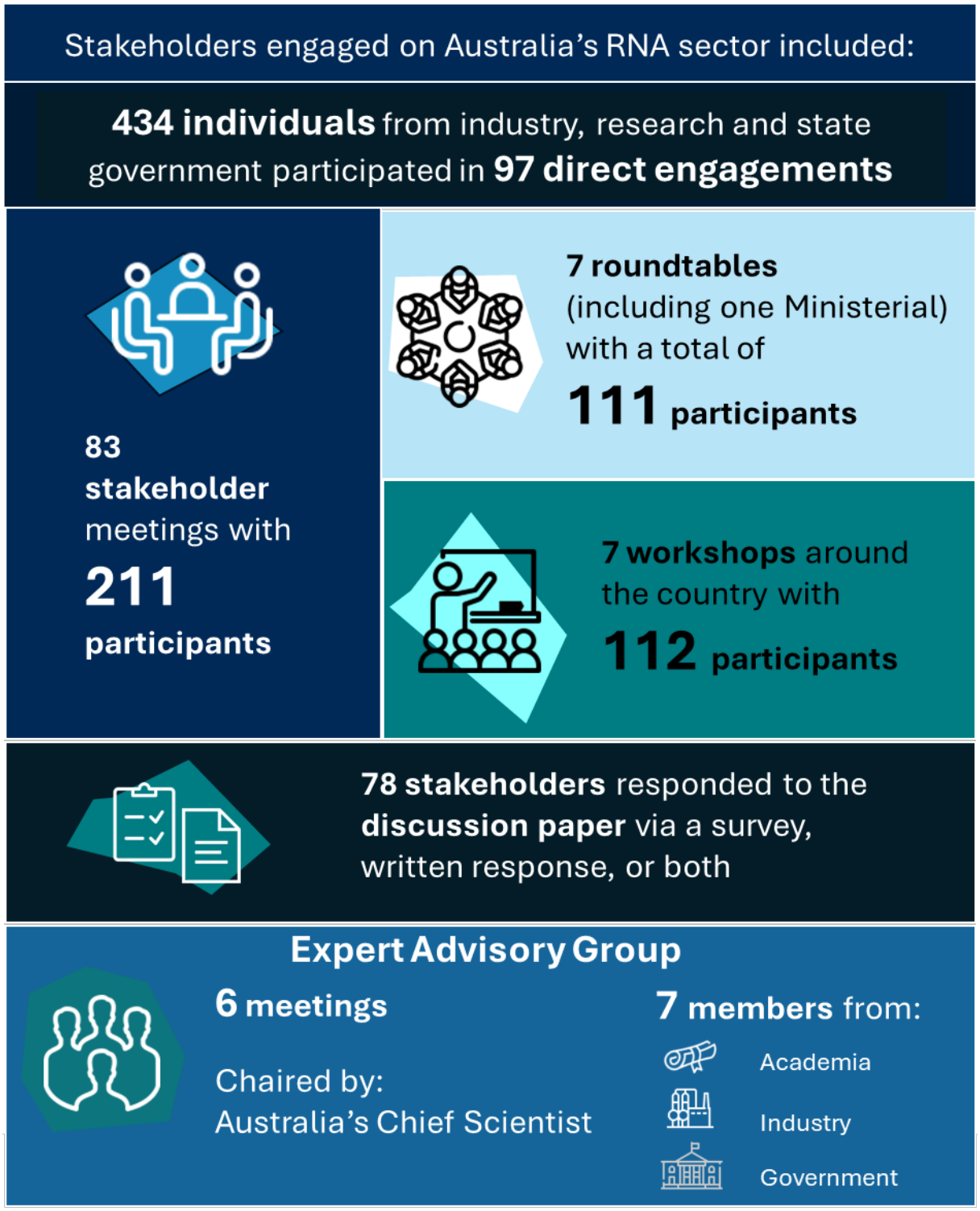
Pursue opportunities to encourage or support international RNA research collaborations in Australian Government competitive grant or funding programs. As an initial step, we could work with the Global Science and Technology Diplomacy Fund to encourage research-led RNA collaborative research projects to apply.

Other potential activities could include possible infrastructure sharing, harnessing shared interest to work on common human and key animal diseases, including to address regional biosecurity challenges and support ongoing surveillance to identify emerging threats, and promoting regulatory alignment between jurisdictions.

What we heard

Who and how did we engage

Throughout 2023, the department consulted with stakeholders, including through issuing a discussion paper, *Understanding our RNA potential*, to learn about the challenges and opportunities for Australia's RNA sector.



The department heard from:

- academic and research institutions
- industry, including pharmaceutical and biotechnology companies
- peak bodies (or learned institutions)
- investors
- advocacy groups
- government agencies.

Since the RNA sector in Australia is still establishing itself, most stakeholders are developing new technologies. It was not unexpected that the largest proportion of stakeholders who provided feedback, about half, were RNA researchers, scientists or academics. About a third were from industry, already putting the ideas into reality, and the rest were from the other categories listed above.

What did we hear?

The consultations identified opportunities for Australia's RNA sector to benefit society and the economy. Trust, skills, translation and commercialisation support, and financial barriers were challenges identified for Australia's RNA sector to overcome to realise its potential.

Improved coordination and collaboration across the RNA ecosystem

Stakeholders identified a strong need for improved coordination and collaboration across the RNA ecosystem. A disconnect between industry and researchers was also noted. Stakeholders felt that improved coordination and collaboration would ensure we have a national RNA sector with a 'Team Australia' mindset. This view is supported by all state governments. Creating an improved national framework and more linkages between precincts would help Australia build capacity, capabilities and lead to success in commercialising new RNA products.

Stakeholders highlighted the significant role played by leading networks of RNA research institutes. These institutes have a history of collaboration and advancing the development of RNA therapeutic treatments within the country, and provide a facilitatory and educative role on RNA technologies to researchers.

Ongoing need for social licence for RNA technologies

Building social license and public acceptance of RNA technology is important to ensure ongoing social licence for RNA medicines. Independent, transparent information and community engagement on the safety and benefits of RNA technology will help improve public and investor confidence. Stakeholders agreed no one sector can assume this role, and a multi-pronged approach is needed involving all stakeholder groups, including end users such as clinicians, patient advocacy groups and farmers.

Australia needs to improve translation of RNA science and research into commercial products

Stakeholders consider that while Australia boasts strong capabilities and expertise in RNA R&D, we need to improve the translation of our excellent RNA research into commercial products. Stakeholders talked about the complexities involved in navigating the regulatory landscape, securing

funding for clinical trials and establishing strategic partnerships for commercialisation all contributing to the difficulty in translating RNA science. The next 10 years will be crucial to position Australia as a major player in the global RNA therapeutics landscape.

A scattered approach and risk-aversion to funding affects not only RNA research but also clinical trials, commercialisation and talent development and attraction. The department heard that Australia is an attractive destination to conduct early-stage clinical trials when compared to other international jurisdictions, particularly due to our Clinical Trials Notification pathway and generous R&DTI which covers eligible clinical trials activities through a Clinical Trials Determination.[10] However, compared to other similar locations the costs associated with clinical trials in Australia can be higher, which may deter researchers and sponsors from choosing Australia as a destination for RNA research. In addition, IP is often lost to overseas organisations during the Phase 2 and 3 clinical trials stage.

Australia needs more commercial investment into the sector

Stakeholders raised that Australia needs more commercial investment into the sector. They noted there is no shortage of capital overall, but there are challenges for the biomedical and RNA sectors in accessing this. There are also challenges in ensuring a sufficient flow of 'investible' companies capable of scaling up and having a pathway to market.

In terms of funding, stakeholders were aware that Australian and State government funding is available for RNA R&D and commercialisation through government backed venture capital organisations but raised that there is a need for greater private venture capital support. In addition, stakeholders said that it would be advantageous if individual grant amounts could be higher and funding was allowed to be spent in multiple jurisdictions and over a longer time frame. The Australian Government's introduction of the NRF was commenced.

Stakeholders stated that smaller companies play a significant role in developing new therapeutic approaches, given the diverse potential of RNA technology to mitigate a wide range of diseases. An entrepreneurial culture is needed to spur development of start-ups and spin-off companies, for example, through incubators, accelerators and entrepreneurship programs, including the IGP.

There are supply chain gaps for key inputs in the sector

Supply chain gaps were identified for key inputs, including a lack of small batch GMP grade RNA for Australian clinical trials and access to, and cost of, raw materials to make RNA and LNPs.

Stakeholders raised that there are hundreds of inputs and multiple conversion points in the process to manufacture RNA products, and that Australia may not be able to onshore them all. It was also raised that there are some constraints on availability of RNA research inputs, such as appropriate precursors to RNA trials, availability of non-animal and animal models, and lengthy administrative processes to comply with biosecurity measures for imports. Stakeholders said there is a need for greater supply chain development to establish a full end-to-end RNA ecosystem in Australia.

The need for Australia to strengthen its domestic small-scale GMP manufacturing capabilities to support access to key inputs and support manufacturing at scale was also raised. The manufacture of small-scale batches of GMP grade mRNA product for use in clinical trials and to support personalised medicine is a barrier in Australia. There is also a need to develop the capability to scale-up

[10] Industry Research and Development (Clinical Trials) Determination 2022 (Cth) provides binding advice about the law is interpreted and applied in relation to the R&DTI; Clinical trials determination guide. Accessed 13 February 2024.

manufacturing of, and encourage wider access to, facilities certified to produce GMP RNA products for later stage clinical trials.

Australian RNA sector needs to engage internationally

During the consultations, the department heard that the Australian RNA sector needs to engage internationally on research and research infrastructure, and on investment and product development. Australian start-ups must focus on global markets from day one to succeed.

Australia is well positioned to build partnerships with countries such as New Zealand, USA, Indonesia, Japan, South Korea and India to expand our capabilities as a nation, capitalise on our strategic and geographical advantages, and address market size and demand issues associated with the commercialisation of RNA medicines.

Stakeholders consider that Australia has an opportunity to lead RNA technology development in the Asia-Pacific region. Australia and the Asia-Pacific's similar climates provide an opportunity to attract investment for commercialisation of RNA therapeutics to address tropical and infectious diseases.

Stakeholders also consider there is high potential to leverage international partnerships to produce RNA products to protect against regional biosecurity risks and that Australia should be focusing on the opportunities from the large emerging markets in our region.

Opportunity for Australian regulatory excellence in RNA platform technology

Stakeholders consider Australia has a robust regulatory pathway for clinical trials, and the safety and efficacy of experimental treatments provides confidence in the scientific conclusions reached in domestic clinical trials. There is an opportunity for Australia to lead development of RNA regulatory frameworks and guidance material.

Stakeholders consider the Therapeutic Goods Administration (TGA) is one of the most well-respected regulators of diagnostic tests, medical devices and medicines globally. However, they raised that Australia needs to develop robust, yet streamlined, regulatory and reimbursement frameworks and industry stakeholders want to be involved in their co-design.

Stakeholders also raised that all clinical trials conducted in Australia follow International Standards Organisation good clinical practice standards. As such, Australian clinical data and results are accepted by international regulatory agencies including the US Food and Drug Administration and European Medicines Agency. However, ethics committees need access to independent RNA experts to expedite clinical trial approvals.

Skills gaps need to be addressed

Industry stakeholders indicated they are keen to be involved in developing and providing workforce skills training opportunities for current and potential future workers, particularly as Australia faces a challenge to achieve breadth and depth in its RNA workforce. There are a small number of highly skilled and specialised professionals with deep expertise in RNA and basic science research, but our workforce is lacking breadth across the value chain of the RNA ecosystem; skilled individuals are needed across the entire RNA ecosystem, at all levels. Stakeholders said the sector needs to attract experienced skilled workers and drug development scientists to help lead Australia's RNA sector growth.

Stakeholders also noted a global shortage of GMP skills. Vocational education and training (VET) pathways for these skills in Australia could further enhance our attractiveness as an RNA investment

destination. Efforts should focus on establishing entry-level skills, up-skilling existing staff and preparing new workforce members to enter the RNA sector with product development, translation, commercialisation, IP, regulation, quality control and practical GMP manufacturing skills. Overall, stakeholders noted that we need to maintain our pipeline of high-quality science, technology, engineering and mathematics (STEM) skills to attract international investment. Skills in enabling technologies that underpin the biotechnology sector, for example artificial intelligence (AI), machine learning (ML) and bioinformatics, are also required.

Abbreviations and glossary

Abbreviation/Acronym	Full Form
AEA	Australia's Economic Accelerator (Cth)
AI	Artificial Intelligence
APVMA	Australian Pesticides and Veterinary Medicines Authority (Cth)
CRC	Cooperative Research Centres
CSIRO	Commonwealth Scientific and Industrial Research Organisation (Cth)
DNA	Deoxyribonucleic acid
GMP	Good Manufacturing Practice
IGP	Industry Growth Program (Cth)
IP	Intellectual Property
JSA	Jobs and Skills Australia (JSA)
JSC	Jobs and Skills Council
LNP	Lipid nanoparticle
MISA	Manufacturing Industry Skills Alliance, a Jobs and Skills Council
MRFF	Medical Research Future Fund (Cth)
mRNA	Messenger RNA
NCRIS	National Collaborative Research Infrastructure Strategy
NHMRC	National Health and Medical Research Council (Cth)
NMA	National Mutual Acceptance
NRF	National Reconstruction Fund (Cth)
OGTR	Office of the Gene Technology Regulator (Cth)
R&D	Research and development
RNA	Ribonucleic acid
STEM	Science, Technology, Engineering and Mathematics
TIA	Therapeutic Innovation Australia
TGA	Therapeutics Goods Administration (Cth)
VET	Vocational Education and Training

Term/phrase	Definition
Base pairing	Base pairing is the way nucleotides connect or 'pair up' with each other when strands of nucleic acids (DNA or RNA) interact with each other. The five different types of nucleotides make up nucleic acids are represented by the letter codes A (adenine), T (thymine), G (guanine), C (cytosine) and U (uracil) – A always pairs with T (DNA) or U (RNA), and G always pairs with C.
Biobank	Collection of biological specimens and related donor information established and made available to support research activities.

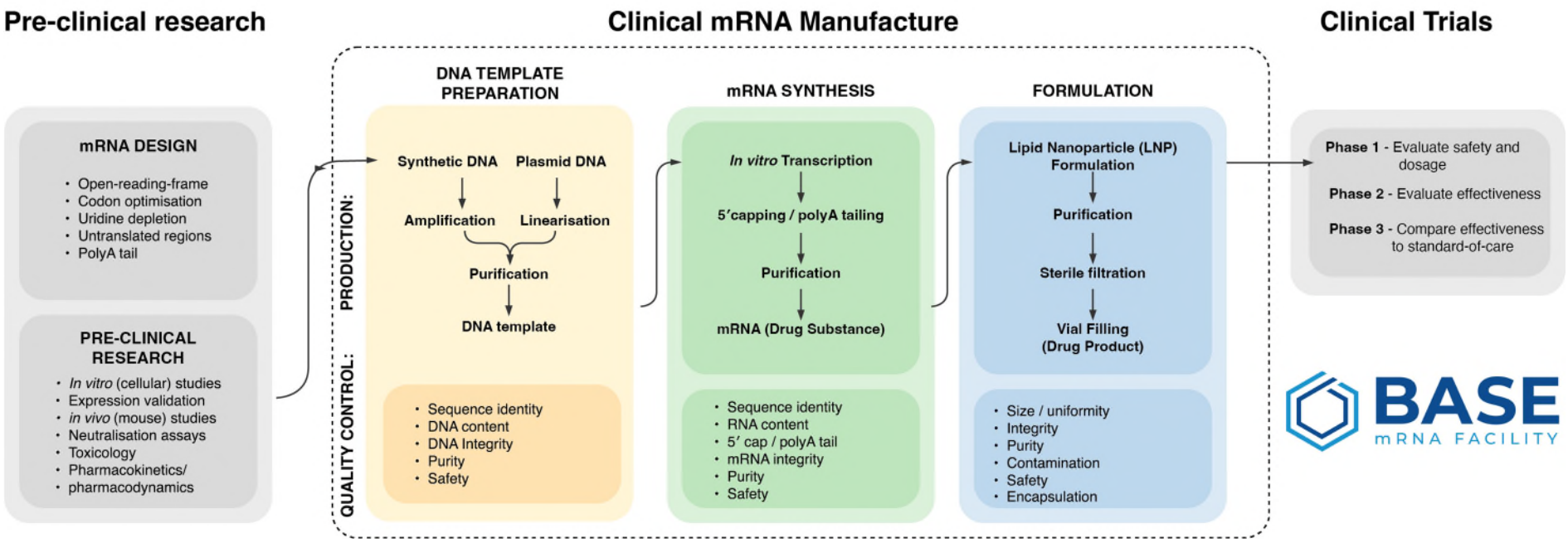
Commercialisation	Follows research translation and is the process of taking a product to market.
Contract Development and Manufacturing Organisation	Is a third party that handles all of the innovation and development work, and manufacturing of a therapeutic or drug substance.
DNA	DNA is made up of two strands of nucleotides and forms chromosomes. Genes are specific sections of DNA that encode sequences (instructions) for proteins. Other sections of DNA control when, where and how much of the protein is made.
Exosome	Subset of nano-sized extracellular vesicles originating from endosomes and mediate cell-to-cell communication.
Gene expression	The process where the instructions in DNA are turned into a function product, such as a protein.
Good Manufacturing Practice (GMP)	Good Manufacturing Practice is a set of principles and procedures to ensure therapeutic goods are produced consistently and to a quality standard appropriate to their intended use (e.g. clinical trial or product specification).
Lipid nanoparticles (LNP)	Lipid nanoparticles are very small particles made of lipids and are used to deliver drugs in the body. A lipid envelope (or sphere) surrounds the drugs to be delivered.
Lipids	Carbon based molecules that do not dissolve in water.
Non-animal model	A subset of biological models using human-derived or humanised cells, tissues or data.
Nucleic acids	Nucleic acids are molecules that store genomic information and are essential to all known forms of life. They consist of strands on nucleotides.
Nucleotides	Nucleotides are organic molecules that form the basic building blocks of nucleic acids (DNA and RNA). There are five types of nucleotides used in nucleic acids, represented by letter codes A (adenine), T (thymine), G (guanine), C (cytosine) and U (uracil).
Oligonucleotides	Short strands of laboratory made nucleic acids used for a wide range of purposes. Oligonucleotides are different to short RNA or DNA as they can include modified nucleotides not found in nature.
One Health	The importance of using a collaborative approach across human, animal, plant and environmental health for disease prevention and management.
Platform technology	A group of technologies used as a base upon which other applications, processes or technologies are developed. A manufacturer uses a platform(s) to develop a vaccine/therapeutic. Term equally applies to a particular drug-delivery system where there is no change. Term considered appropriate when: (a) manufacturing methods are essentially unchanged (but may be optimised for each specific vaccine/therapeutic); (b) test methods (except for identity, potency and stability) and acceptance criteria are unchanged; (c)

	immunomodulatory components are unchanged; and (d) compliance with GMP is unchanged.[11]
Protein synthesis	The process where cells make proteins.
Proteins	Large molecules containing one or more long chain(s) of amino acids and serve essential functions in the body, e.g. enzymes, antibodies, transport channels.
Regulatory science	Is the science of developing tools, standards and approaches to assess the safety, efficacy, quality and performance of products for regulatory approval.
Research pipeline	The journey of translating a discovery into improved health outcomes.
Research translation	The process whereby knowledge is passed anywhere along the translational pathway from basic science at one end to developed product.
Ribosome	Part of the cellular machinery that reads the information from mRNA and uses the information to translate new proteins.
RNA	RNA is a single stranded copy of the genetic information contained within DNA. There are many types of RNA – mRNA carries the instructions to make proteins; other RNAs can prevent proteins from being made.
Social licence	Describes the level of approval from community for certain sectors to carry out activities requiring more than regulatory approval.
Transcription	Transcription is a process where a segment of DNA is copied into mRNA.
Translation	Translation is a process where ribosomes read the information in mRNA and use it to make a protein
Translational Research	Any type of research leading to knowledge translation.
Zoonotic disease	An infectious disease that is transmitted between species from animals to humans (or from humans to animals).

[11] WHO (2022) *Annex 3 Evaluation of the quality, safety and efficacy of messenger RNA vaccines for the prevention of infectious diseases: regulatory considerations*. WHO Technical Report Series No. 1039, p 94.

Appendix A: RNA technologies and use

mRNA product development workflow



Source: A/Prof Tim Mercer and Dr Seth Cheetham, BASE mRNA Facility, UQ (November 2023)

RNA technologies

RNA Technology	**Description**	Action	Human/Animal Disease Use
antisense oligonucleotide (ASO)	Synthetic single stranded RNA that is complementary to a mRNA	Two alternate actions: 1. regulate gene expression by blocking translation process (silencing) 2. restore synthesis of a missing protein by splicing modulation	Personalised treatments for genetic diseases
antisense RNA (asRNA)	Type of non-coding RNA – can be considered sncRNA or lncRNA depending upon its length	Interferes with function of mRNA by base pairing, interrupting the translation process	Anticancer and antivirus treatments
double-stranded RNA (dsRNA)	Exists in double-strands	Interacts with proteins involved in gene regulation and RNAi processes	Vaccines
messenger RNA (mRNA)	Single-stranded RNA	Transfers genetic information from the DNA in the nucleus to the cytoplasm, where proteins are synthesised (on the ribosomes)	Vaccines and gene therapy
RNA interference (RNAi) [including small interfering RNA (siRNA) and micro RNA (miRNA)]	Sub-group of sncRNA siRNA: double-stranded RNA, typically 20–24 (normally 21) base pairs in length, often laboratory made miRNA: small, single-stranded, non-coding RNA containing 21–23 bases	siRNA*:* target a specific mRNA to prevent protein synthesis miRNA*:* target multiple mRNAs to regulate expression of different genes at the same time. Either a miRNA mimic (replacement therapy) or antimiRNA (inhibition of miRNA function)	siRNA: biological drugs and therapeutic agents miRNA: therapeutic agents
RNA aptamers	Single stranded oligonucleotides that fold into defined 3D structures	Binds proteins inhibiting protein–protein interactions	RNA based drugs to treat prostate cancer and HIV. Has the potential to be used as an imaging tool in clinical diagnosis

ribosomal RNA (rRNA)	Four rRNAs and 80 ribosomal proteins (RPs) make up the ribosome	The ribosome is a multi-unit complex that translates mRNA into protein	Therapeutic target as rRNA synthesis commonly dysregulated in cancers
transfer RNA (tRNA)	Small, non-coding RNA	Transports amino acid to the ribosomes for translation	Suppressor tRNA therapies
circular RNA (circRNA)	Single stranded RNA that is covalently closed	Regulation of gene transcription	Potential use as disease biomarkers
self-amplifying RNA (saRNA)[12]	Positive sense single stranded RNA	Mimics a viral infection and signal for protein synthesis	Vaccines
small activating RNA	Double stranded RNA with 19-21 base pairs	Recruits RNA induced transcriptional activation complex to promoter selectively increasing gene transcription	Vaccines
prohead RNA (pRNA)	Essential component in the assembly and operation of the bacteriophage-29 DNA packaging motor	Involved in DNA encapsulation of bacteriophage-29 of *Bacillus subtilis*	Potential applications in gene regulation to treat cancer
short non-coding RNA (sncRNA)	Less than 200 nucleotides in length and do not code for proteins	Interact with other nucleic acids to regulate gene expression and cellular processes	Potential use as disease biomarkers
long non-coding RNA (lncRNA)	More than 200 nucleotides in length and do not code for proteins	Regulate gene expression Can also fold into 2D or 3D structures (like loops) to facilitate different types of interaction with cellular machinery	Therapeutic targets and potential biomarkers for lipid-related diseases
exosomal RNA	Exosome cargo can include mRNA, miRNA, lncRNA and circRNA	Have cell specificity and reflect conditions of originating cell	Potential use as disease biomarkers
small nuclear RNA (snRNA)	~100–300 nucleotides in length, localised to the nucleus	Involved in RNA processing and splicing of introns from primary genomic transcripts	Proposed as potential diagnostic biomarkers in various tumour types,

[12] Also known as self-replicating RNA.

			including pancreatic cancer and colorectal cancer
RNA base modification	Chemical modification to the nucleic acid base; ribose sugar; or sugar-phosphate backbone		Improve stability and half-life Improve target specificity
RNA nanocarriers, including cell targeting	Potential nanocarrier candidates include lipids, polymers, peptides, nanoparticles of various materials, exosomes and quantum dots	An ideal nanocarrier should have low-toxicity, biodegradability and biocompatibility	Protect against degradation Cellular delivery and uptake

Appendix B: Existing policy, programs and investment

Table 2 summarises existing policies, programs and investments that can contribute to the growth of Australia's RNA sector and highlights current reviews and initiatives that will impact this blueprint as they are delivered.

Table 2: Existing policy, programs and investments enabling Australia's RNA sector

Goal 1: Connect and promote our national RNA ecosystem
A number of Australian Government programs provide financial support for collaborative research. The proposed RNA Growth Leadership Initiative will promote broader collaboration across the whole ecosystem. The National Collaborative Research Infrastructure Strategy (NCRIS) and 2021 National Research Infrastructure Roadmap will be an important element of Action 1.1 given its collaborative approach to national research infrastructure delivery and priorities established for future investment. For instance, the roadmap identified: • the need for biologics development facilities to support basic and translational research – this is currently being addressed by Therapeutic Innovation Australia's (TIA) RNA capability • that Australia has numerous collections, including biobanks, that, while critical for advancing research discovery, are uncoordinated and their potential is unrealised such as discovering genetic disease causes and advancing personalised medicine. A biobanks scoping study is being planned.[13]
Goal 2: Increase skills and access to infrastructure
Existing skills development initiatives for RNA or GMP include: • The Monash Centre for Advanced mRNA Medicines Manufacturing and Workforce Training (Vic) will deliver best-practice education and training programs across the mRNA pipeline including manufacturing, biochemical engineering, production, LNP and fill/finish processes. • The University of Technology Sydney's (UTS) Biologics Innovation Facility is a GMP bioprocessing teaching and training facility. It is designed to drive opportunities to upskill and scale-up biopharmaceutical projects using state of the art single-use equipment and industry's best practice processing techniques. • Queensland's BioManufacturing Alliance[14] intends to address its biomanufacturing skills gaps, including RNA.

[13] Department of Education, National Research Infrastructure Scoping Studies (last modified 19 May 2023) < https://www.education.gov.au/national-research-infrastructure/national-research-infrastructure-scoping-studies> Accessed 24 August 2023.

[14] As at 1 November 2023, members are Life Sciences Queensland, QIMR Berghofer Medical Research Institute, the Translational Research Institute, University of Queensland, Cytiva, Springfield City Group and Thermo Fisher Patheon.

- The NSW Government GMP Future Workforce Roundtable brings together key stakeholders to discuss future GMP workforce needs, current training pathways available and ways to manage skill gap risks. Participants are from across Australia, including government, industry, research and education organisations.
- The $296 million National Industry PhD Program supports PhD candidates to undertake industry-focused research projects whilst developing knowledge and skills to better translate university research into commercialisation outcomes.
- The NSW RNA Future Leaders Program provided $2.9 million to early-mid career researchers in RNA diagnostics, therapeutics and vaccines to support emerging research leaders.
- MTPConnect is delivering the Industry Doctoral Training Centre for the Biomanufacturing PhD+ Program to support industry based training, and has already placed students at BioCina (SA) and CSL (Vic).

In partnership with universities, research agencies, State and Territory governments, and industry, the Australian Government's NCRIS delivers cutting edge national research infrastructure. NCRIS infrastructure are included in the Capability Network Index. Further funding was recently provided to the following NCRIS programs, all of which are mRNA technology enablers:

- TIA ($31.3 million) to continue manufacturing support, providing a bridge between bench researchers and large scale initiatives. A portion of funding will be used to establish RNA Products Capability across four nodes – WA, Qld, Vic and NSW – building off the success of the UQ's BASE
- Bioplatforms Australia ($113 million) to enhance national research infrastructure laboratories and bioinformatics capability, expand synthetic biology capability will have significant impact on the design and analysis of RNA constructs, and a national translation human genomics data initiative will support RNA biology
- Phenomics Australia ($15.8 million) provides mouse and in vitro models for disease study.

Workforce planning will need to take account of work underway in the skills and education landscape:

- Changes to skilled migration as the result of the Migration Strategy.[15] This includes the introduction of the new National Innovation Visa by the end of 2024 to attract highly skilled individuals.
- The VET sector's approach to delivering immediate, medium and long-term skills to support industries of the future, including RNA manufacturing. These changes are expected as the result of the Employment White Paper (e.g. new degree apprenticeship qualifications); the Universities Accord Review of Australia's Higher Education System (Accord); the National Skills Agreement; and the complementary Jobs and Skills Australia (JSA) and Jobs and Skills Councils (JSC). The manufacturing industry's JSC is the Manufacturing Industry Skills Alliance.
- Outcomes arising from the Department of Health and Aged Care's independent audit of the health and medical research workforce.

[15] Commonwealth of Australia, *Migration Strategy 2023*.

Goal 3: Improve research, translation and investment

Numerous Australian and State governments programs support basic research and translation, including in medical science, nanotechnologies and biotechnologies, across the university and industry sectors (especially small and medium sized enterprises).

Other possible changes to the funding landscape and national human and animal health priorities from the following reforms will be explored to identify options for further research efforts to drive innovation in the RNA sector and adjacent technologies:

- optimised alignment and coordination between the Medical Research Future Fund (MRFF) and NHMRC's Medical Research Endowment Account (MREA)[16]
- finalisation of the revitalised National Science and Research Priorities and the National Science Statement.

Australian Government programs include:

- $15 billion National Reconstruction Fund (NRF)
- $392.4 million Industry Growth Program (IGP)
- $1.6 billion Australia's Economic Accelerator (AEA)
- MREA
- MRFF
- CSIRO (ON Accelerate).

There are various RNA specific or RNA prioritised State funding programs. The Victorian Government has provided $27 million in research grant program funding across 42 mRNA medical research projects in diseases including cancer, liver disease and Alzheimer's Disease. The NSW Government has committed $119 million over 10 years towards RNA research and development.

Academia, industry and investors similarly have a number of programs supporting research and/or research translation:

- Discovery-stage, incubator or accelerator programs exist to support proof-of-concept (usually pre-company formation) or early-stage biotechnology companies to gain access to expertise, funding and (potential) investor introductions. Additionally, university technology transfer offices support the commercialisation of research, including supporting related skills development and identifying funding opportunities for research translation. The discovery-stage, incubator or accelerator programs exist to support proof-of-concept (usually pre-company formation) or early-stage biotechnology companies to gain access to expertise, funding and

[16] Department of Health and Aged Care, Improving alignment and coordination between the Medical Research Future Fund and Medical Research Endowment Account.

(potential) investor introductions. Additionally, university technology transfer offices support the commercialisation of research, including supporting related skills development and identifying funding opportunities for research translation.

- The UNSW RNA Institute includes the RNA Accelerator has pre-clinical manufacturing capability in RNAs and formulation. UNSW is also developing the Health Translation Hub to improve translation success.
- The NSW RNA Production and Research Network provides materials, services and support to translate newly developed RNA therapeutics from the bench to advanced pre-clinical studies.
- Qld's Translational Science Hub which leverages UQ and Griffith University capabilities to, with Sanofi, optimise mRNA platform technology and advance vaccine development.
- The Monash-Moderna mRNA Quantitative Pharmacology Accelerator[17] focuses on quantitative pharmacology use to accelerate mRNA medicines development.
- The mRNA Platform Incubator Network[18] aims to advance mRNA medicine, foster scientific excellence in clinical translation in Australia and further the therapeutic potential of the mRNA platform.
- The Victorian Government, La Trobe University and BioNTech's partnership will establish an innovation centre[19] to support the commercialisation of local research.

The following actions also support research and/or research translation:

- Clinical trials
    - The National One Stop Shop for Clinical Trials and Health-related Human Research consultation report[20] sets out the process to develop a national health-related human research Information and Communication Technology (ICT) platform. The sector and jurisdictions note that the National One Stop Shop Program (and its public facing National Clinical Trials Front Door) presents a transformative opportunity to improve Australia's global clinical trials positioning[21] and improved visibility of current RNA trials with Australian participation. The 2024–25 Budget provided $18.8 million for a National One Stop Shop to streamline administration and regulation of health and medical research, increasing the number of Australian clinical trials and helping patients get early access to promising treatments.

[17] A partnership between Moderna and the Monash Institute of Pharmaceutical Sciences.
[18] As at 2 November 2023, members are Moderna, Monash University, Monash Institute of Pharmaceutical Sciences, the Peter Doherty Institute of Infection and Immunity (a joint venture of the University of Melbourne and the Royal Melbourne Hospital), Peter MacCallum Cancer Centre, the Murdoch Research Children's Institute and Doherty Clinical Trials Limited.
[19] Premier of Victoria Hon Jacinta Allan MP, BioNTech Partnership to Deliver Next Generation Cancer Care (Media Release, 8 December 2023).
[20] Australian Commission on Safety and Quality in Health Care (2022) *Consultation Report Requirements for the National One Stop Shop, the National Clinical Trials Front Door and core elements of the National Site-Specific Assessment*.
[21] Australian Commission on Safety and Quality in Health Care (2022) *Consultation Report – Requirements for the National One Stop Shop, the National Clinical Trials Front Door and core elements of the National Site-Specific Assessment*.

    - Jurisdictions are collaborating to further strengthen Australia's clinical trials sector by making it easier for patients, researchers and sponsors to find, conduct and participate in clinical trials and research. It will also make it easier to invest and conduct research in Australia.
    - The National Mutual Acceptance (NMA) scheme for Ethical and Scientific Review of Multi-Centre Research is a key enabler for clinical trials and research conducted in Australia. Work is underway to develop an accreditation scheme for ethics committees participating in the cross-jurisdictional NMA scheme. This will ensure NMA accredited ethics committees operate to the high quality and safety levels expected in Australia. National consultations to inform the accreditation scheme for NMA Human Research Ethics Committees (HREC) commenced in August 2023 and are being conducted by the Australian Commission on Safety and Quality in Health Care (ACSQHC).
- Small batch GMP-grade RNA facilities are being delivered in Australia
    - Macquarie University's (NSW) RNA Research and Pilot Manufacturing Facility (expected to be completed and operational in 2025): will produce a wide range of RNA therapeutics and potential delivery technologies.
    - UQ's BASE mRNA facility is expanding its capability from experimental grade RNA medicines to produce mRNA vaccines and therapies for clinical trials by developing end-to-end capabilities.
    - BioCina (SA) is developing mRNA manufacturing at clinical trial scale, and, in collaboration with industry and academic partners, Cytiva and the University of Adelaide, is developing precision manufacturing processes and capabilities for RNA.
    - In WA, a consortium is investigating establishing a capability for producing GMP chemically synthesised (short) RNA and the University of Western Australia's (UWA) Australian Centre for RNA Therapeutics in Cancer, launching in 2024, includes a mRNA (and other forms of long RNA) production facility for pre-clinical grade RNA therapeutics in cancer.
    - BioNTech's (Vic) clinical-scale mRNA manufacturing facility at La Trobe University will produce novel mRNA based therapies for clinical trials (e.g. rare cancers), and research-grade RNA materials.
- NCRIS Infrastructure, including that provided by TIA, Bioplatforms Australia, Phenomics Australia, the National Imaging Facility and the Population Health Research Network.
- Health Technology Assessment Policy and Methods Review is reviewing methods for evaluating all medicines and vaccines, and highly specialised therapies (arising from new and emerging technologies), and the suitability of existing funding pathways. Its goal is to ensure assessment processes key pace with advancing health technology and minimise barriers to access.
- The National Measurement Institute can produce RNA reference material to support biological measurement activities.

Goal 4: Lead RNA regulation and guidance development

TGA, OGTR and APVMA engage internationally to promote and develop regulatory alignment and best practice regulatory science. They all provide regulatory assistance to enterprises using emerging technologies such as RNA technologies. This assistance can be in person or in the form of guidelines. For example, APVMA has published several specific guidelines (based on international developments) advising on the registration of veterinary vaccines and immunobiological products, including novel technologies such as mRNA vaccines

For instance, TGA:

- is a member of the Australia-Canada-Singapore-Switzerland-United Kingdom (Access) Consortium which seeks to promote greater regulatory collaboration and alignment of regulatory requirements between each other
- participates in the International Coalition of Medicines Regulatory Authorities (ICMRA) which seeks to improve international regulatory collaboration, improve communication and address shared regulatory challenges.

In addition, the Department of Health and Aged Care is addressing the recommendations of the Third Review of the National Gene Technology Scheme, endorsed by the (now) Gene Technology Ministers' Meeting. The Review identified the need to provide improved regulatory certainty for emerging technologies.

The Australian Centre for Disease Control is being established to improve Australia's response and preparedness for public health emergencies, and will contribute to harmonising regulation between jurisdictions by supporting regulators.

Goal 5: Build and strengthen international partnerships

Australia engages in numerous international bi- and multi-lateral fora that identify and support research projects of mutually strategic benefit – these fora target technology advancement (e.g. Global Science and Technology Diplomacy Fund (GSTD Fund)), regulation, hazard preparedness and response (e.g. Medical Countermeasures Consortium), and disease prevention and research (e.g. NHMRC's collaborative bilateral and multilateral arrangements). Similarly, Australia's ongoing participation in international conferences (such as BIO) is already leveraged to promote Australia as an investment destination and excellent collaborative partner.

Action 5 will promote RNA research and regulatory science collaborations in these (and other) international bi- and multi-lateral fora, such as recently done in the GSTD Fund's Australia–India Strategic Research Fund Round 15 (2023) and Strategic Element Round 1 (2024) which identified RNA (including mRNA) vaccines and therapies as a priority area.