



Australian Government
Department of Industry,
Science and Resources

Understanding our RNA potential

Discussion paper

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Executive summary

This discussion paper seeks your views on the potential of Australia's RNA sector.

RNA (ribonucleic acid) technology is a subfield of biotechnology. The use of RNA in modern technologies rose to global prominence in 2020. Messenger RNA (mRNA) vaccines formed a critical part of the response to the COVID-19 pandemic. But RNA has greater potential. It is essential to every living organism and its potential to drive innovation and growth in biotech, medicine and agriculture is extensive. An exciting new range of RNA treatments is emerging. These include:

- treatments for cancer and cardiovascular disease
- regenerative medicines and vaccines for influenza in humans
- vaccines for foot-and-mouth disease and lumpy skin disease in animals.

Our track record in RNA is impressive and our RNA sector is set to grow. Some of the critical breakthroughs that led to development of mRNA vaccines were made in Australia, notably the discovery of the Shine–Dalgarno sequence. Australia is also home to world-leading scientists and healthcare professionals. We have high quality medical and agricultural research and healthcare infrastructure, a stable political, regulatory and socioeconomic environment, and a strong intellectual property (IP) regime.

The Australian Government has partnered with Moderna and the Victorian Government to build a population-scale mRNA vaccine manufacturing facility in Melbourne. This is a game changer for our RNA sector. Australia will be one of few countries in the world – and the first country in the southern hemisphere – with commercial mRNA manufacturing capability. In concert with Myeloid Therapeutics, the NSW RNA Pilot facility at Macquarie University will make RNA therapies for humans and mRNA vaccines for animals. Combined with other state and territory government and commercial investments – including BioCina's manufacturing capability in South Australia, and Sanofi's research and development hubs in Queensland – the commercialisation pathway for RNA will strengthen over the next decade. These developments will position Australia as a major player in the Asia-Pacific region, with significant potential for growth and innovation in the future.

Australia's RNA sector is already making an impact and could be at the forefront of developing and producing next generation RNA technology. It could deliver advanced manufacturing, sovereign capability and local jobs. But there are challenges to overcome, including improving commercialisation, national coordination, workforce skilling and making the most of our infrastructure.

This is why the Department of Industry, Science and Resources (the department) is developing advice for the government on the potential of the RNA sector.

This discussion paper details some initial findings on challenges and opportunities for RNA in Australia to start the conversation. But your engagement is critical. Your views will ensure our advice is grounded in robust evidence that includes your expertise, values and know-how.

We welcome your views on the topics and questions in this discussion paper.

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Purpose

RNA technology has many potential applications to address human, animal and plant health, and biosecurity issues. The department has completed desktop research and preliminary consultations with a range of Australian academia, industry and government stakeholders to build our understanding of Australia's RNA sector and its growth potential.

This discussion paper is the next step in supporting advice to government on Australia's RNA sector. It provides information on challenges and opportunities for developing RNA technology in Australia to inform your feedback. We encourage you to complete the online survey and upload a submission.

We wish to learn more about the areas Australia could focus its RNA scientific research and commercial efforts. For example:

- development of different RNA vaccines and therapeutics solutions for critical diseases (human or animal)
- RNA modalities
- delivery systems.

We also want to understand the full scope of RNA technologies currently under development across Australia.

The department envisages that the advice we provide to government would cover areas such as:

- developing Australia's capabilities in this emerging technology
- capitalising on Australia's world-class research and development
- supporting strong commercialisation prospects
- contributing to competitive industry opportunities with well-paid jobs
- leveraging a critical sovereign capability.

Any further action arising from this consultation process will be subject to the government's consideration of advice.

Questions for discussion

We invite you to take part in the discussion and put forward ideas on the priorities for Australia's RNA sector.

We want to hear from a wide range of perspectives including:

- individual researchers
- university and research institutes
- the medical manufacturing industry and supply chain participants
- health and animal biosecurity experts
- state and territory governments.

Below are some suggested questions which may inform your feedback to us:

1. Please tell us about you or your organisation.
2. What characteristics should Australia's RNA sector focus on building over the next 10 years?
3. What science questions and basic breakthroughs are needed to overcome any roadblocks in the development of RNA technologies?

4. Which elements of the RNA technology development and supply chain should Australia focus on developing sovereign capability in?
5. What are the considerations for successful implementation/uptake of RNA technologies for a sustainable pipeline and to achieve impact?
6. What skills or capabilities are needed to support growth in the sector?
7. Are there any other issues that you would like to raise?

Please submit your feedback [here](#) and we also invite you to complete the online survey, available at consult.industry.gov.au/rnadiscussion.

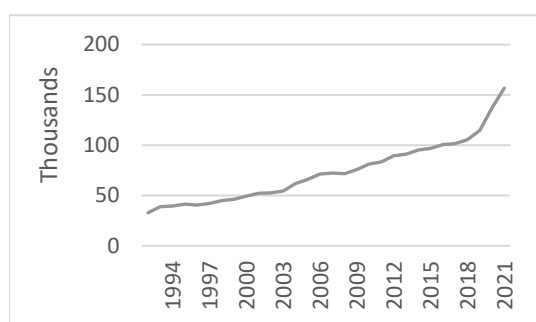
The department intends to conduct face-to-face and virtual meetings with stakeholders during the 8 week consultation period. Please let us know if you would like to receive an invitation by emailing us at onshoremrna@industry.gov.au.

Our RNA sector's unique potential

RNA technology can drive economic growth, well-paid jobs, and secure sovereign health needs

RNA technology is a subfield of biotechnology, with enormous potential to improve medicine and to underpin the development of a new industry. The most familiar RNA technology is messenger RNA (mRNA) vaccines, such as those created by Pfizer-BioNTech and Moderna in response to the COVID-19 pandemic. They differ from traditional vaccines by using RNA genetic code to trigger the production of the COVID-19 spike protein. Immune cells recognise the spike protein as foreign and begin building an immune response against it.

Exhibit 1: Number of publications mentioning RNA recorded in Web of Science (1992–2021). RNA research has grown significantly since 2017.



While mRNA vaccines are a leading example of the benefits of specialising in genomics, RNA technology has much broader potential. RNA is essential to the existence of every living organism, so the potential for innovation and application is extensive. Besides influencing disease in humans, RNA controls development in plants and animals, influencing areas as diverse as crop yields in agriculture to brain function in animals.

mRNA vaccines' recent success has proven RNA technology works. RNA has the potential to be the next wave in medical technology. It is a promising alternative to conventional vaccines and therapeutics because of its:

- safety (mRNA is a non-infectious, non-integrating platform)
- high potency (mRNA can be made more stable and highly translatable, and can be administered repeatedly)
- capacity for rapid development
- potential for low-cost manufacture and safe administration.

RNA vaccines and therapeutics have the potential to treat a range of human diseases, including:

- cancer
- rabies
- zika
- influenza
- tuberculosis

- HIV
- malaria
- cystic fibrosis
- muscular dystrophy
- cardiovascular disease.

They may also be used in animal health, including to prevent clinical signs of animal diseases such as African swine fever and lumpy skin disease.

Although there are many benefits to using RNA technology in vaccines and therapeutics, additional challenges must be considered. Manufacturing consistency, for both the mRNA and the lipid nanoparticles (LNP) is critical. New mRNA vaccines may pose challenges compared to other vaccine types due to, for example:

- comparative reactogenicity
- creation of multivalent products and comparative duration of protection
- maintenance of cold chain in remote areas
- regulatory issues for animal vaccines.

RNA therapeutics could present additional technical and regulatory challenges as they may require higher (or more frequent) dosing, challenges of delivery to target organs and potential need for extra efficacy, safety and quality issues to be assessed.

Australia's RNA sector could grasp the opportunities

Australia is home to world leading scientists and healthcare professionals. It has high quality medical research and healthcare infrastructure, a stable socioeconomic environment and a strong IP regime. Our existing Australian medical manufacturing sector is world-class.

Australia's RNA manufacturing capability includes products beyond mRNA, such as antisense oligonucleotides (ASOs), RNA aptamers, and interfering RNAs such as small interfering RNA (siRNA) and microRNA (miRNA), as well as nanoparticles and other RNA delivery systems. There are also several types of non-coding 'synthetic' RNAs (sRNA),¹ so named because their shorter length allows them to be effectively synthesised using chemical methods.

Australian research has yielded many life-changing and life-saving discoveries. Among them are penicillin-based antibiotics, ultrasounds, in-vitro fertilisation, the bionic ear and a cervical cancer vaccine. Australia ranks eighth globally for life sciences research. The country's world-leading researchers have won 7 Nobel Prizes for their contributions to physiology and medicine. Some of the key breakthroughs that led to the development of mRNA vaccines were made in Australia, notably the discovery of the Shine–Dalgarno sequence,² which plays a critical role in facilitating the initiation of protein synthesis (see Exhibit 2).

However, Australia's relatively small population means it cannot specialise in everything. International research and development partnerships will be critical to building Australian RNA

¹ This includes guide RNA (gRNA), which is a key component in the CRISPR gene-editing technology that is set to revolutionise the treatment of many debilitating genetic disorders and diseases. Shorter length DNA can also be made using the exact same equipment as is required for sRNA. Hybrid sRNA-DNA systems are also a key component in some PCR-related diagnostic technologies, including the intellectual property that underpins the NSW-based diagnostic firm SpeedX

² AAT Bioquest, [What is the significance of the shine dalgarno sequence?](#), AAT Bioquest website, 2023, accessed 24 February 2023

research excellence. For example, the United States and Europe are the dominant destination countries for patent protection with over 60% of all patent families filed since 2000 originating from the United States. The scale of manufacture of human vaccines is also small in Australia by world standards. In contrast because of Australia's strict quarantine rules Australia has large world class vaccine facilities for animals in NSW and Victoria. Complementary investments and international collaborations between businesses and research institutions will help address the challenges in scaling up the delivery of RNA products in accordance with commercial production considerations, requirements and market drivers.

A stronger RNA sector which supported research, production and material inputs for RNA technologies would have positive overflows to Australia's biotechnology sector and help ensure we are better prepared for future pandemics. COVID-19 highlighted the need for Australia to improve sovereign capabilities in the manufacture of essential medical supplies and vaccines, protect food supplies and our important agricultural export industries.

RNA technology is broad and offers many niches in which Australia can be competitive. The mRNA COVID-19 vaccines that emerged in 2020 were built on a series of different discoveries over decades. As we move on from the COVID-19 pandemic, development of RNA products must adjust to consider other health care priorities and commercial mass-scale production requirements. More discoveries in RNA production are likely to further disrupt health care, including more efficient production and logistics, improved thermostability and tolerance levels, and new products to treat diseases other than COVID-19. Better alignment between academia and industry will be important to advance RNA technology improvements and capture the economic and health benefits for Australia.

Exhibit 2: Australia's RNA sector made contributions that were among the building blocks of 2020's mRNA COVID-19 vaccines

In 1973, Lynn Dalgarno, from the Australian National University's Department of Biochemistry, and his then PhD student John Shine, proposed an initiating signal for protein synthesis in prokaryotic cells. This discovery – the Shine-Dalgarno sequence – marks the beginnings of the global biotechnology industry and unlocked the secrets of genetic coding in producing proteins.³

In 1975, Australian scientist Suzanne Cory and American husband Jerry Adams established a laboratory practice within the Walter and Eliza Hall Institute (WEHI) and took molecular biology research in Australia to the world-stage. Within 3 years they had their first big breakthrough – a new insight into the structure of RNA which had a major impact on the understanding of immunology and the development of cancer. Conceiving of mRNA therapeutics would not have been possible without this discovery.

These Australian discoveries were foundational to the world's understanding of the characteristics of RNA, gene expression and protein production, and became critical to the development and delivery of mRNA vaccines and therapies. Other major contributions included:

- Ming-Bo Wang and Peter Waterhouse from CSIRO in Canberra first described RNA-mediated gene silencing in plants in the 1990s.

³ Australian National University, [The Shine-Dalgarno sequence – the beginnings of biotechnology](#), ANU website, 7 February 2017, accessed 15 December 2022

- John Mattick of the University of Queensland (UQ) provided key thought leadership on non-coding DNA (ncDNA) in the 1990s. He found they did have a function: to produce RNA. His work helped usher in the ncRNA revolution.
- In 2017–18, Dr Vihandha Wickramasinghe at the Peter MacCallum Cancer Centre demonstrated that selective mRNA export from the nucleus can regulate a fundamental biological process, DNA repair.

As well as these critical contributions to RNA science, RNA-based vaccines are emerging in Australia. One example is an mRNA-based COVID-19 vaccine candidate created by researchers at the Monash Institute of Pharmaceutical Scientists (the MIPS) in partnership with mRNA Victoria, the Doherty Institute and local manufacturer IDT Australia.⁴ The first volunteers in the vaccine's Phase I trial safely administered their first dose in May 2022. The development of the vaccine and the clinical trial were supported by the Australian Government's Medical Research Future Fund (MRFF). The NSW Department of Primary Industries/Tiba Biotech consortium has showed efficacy of a dendrimer self-amplifying mRNA nanoparticle vaccine against Border disease in sheep.

The Australian Government's partnership with Moderna and Victoria has primed the RNA sector for growth

On 15 August 2022, the Australian Government finalised partnership arrangements with the Victorian Government and pharmaceutical company Moderna to support establishment of Moderna's Australian mRNA production facility.⁵ This world-class mRNA facility will begin operations in late 2024 (subject to regulatory approvals) at Monash University's Clayton Campus in Victoria. This marked the beginning of another exciting new chapter for Australia's RNA sector.

Australia will be one of few countries in the world – and the first country in the southern hemisphere – with a commercial mRNA manufacturing capability supported by Australia's strong track record of expertise throughout the RNA value chain. It will give Australia greater certainty and faster access to vaccines and could reduce the social and economic costs of future pandemics. The partnership also signals the Australian Government's strong support for rebuilding onshore advanced manufacturing, sovereign capability and highly skilled local jobs.

The Moderna partnership is already having an impact and will encourage further development of Australia's broader RNA sector and next generation RNA technology.

For example:

- Moderna's regional headquarters for South-East Asia, Australia and Oceania,⁶ and a Regional Research Centre for Respiratory Medicine and Tropical Disease, will be located in Victoria.⁷

⁴ Monash University, [Monash University announces manufacturing agreement with IDT to produce mRNA COVID vaccine for clinical trials](#), Monash University website, 14 October 2021, accessed 15 December 2022

⁵ Prime Minister Anthony Albanese, Premier of Victoria Daniel Andrews, Minister for Health and Aged Care the Hon Mark Butler MP and Minister for Industry and Science the Hon Ed Husic, [Homegrown vaccines on the way for Australia](#), Joint Media Release, 15 August 2022, accessed 15 December 2022

⁶ Prime Minister, Minister for Finance, Minister for Health and Aged Care, Minister for Industry, Minister for Industry, Energy and Emissions Reduction, [Partnership secures Australian-made mRNA vaccines](#), Joint media release, 24 March 2022, accessed 15 December 2022

⁷ Moderna, [Moderna finalizes strategic partnership with Australian Government](#), Moderna website, 23 March 2022, accessed 15 December 2022

- New collaborations with Australia’s world-class research organisations, including the Doherty Institute,⁸ the Burnet Institute⁹ and the University of Queensland (UQ).¹⁰
- The first round of Moderna’s annual Australian Fellowship Program was open until 30 June 2023 to applications from Australian researchers working on concepts that may help advance mRNA medicines.¹¹

In combination with other state and territory government and commercial investments, including setting up manufacturing facilities and research and development hubs across Australia, the commercialisation pathway for RNA will strengthen over the next decade.

Other Australian Government investments are providing opportunities for the Australian RNA sector to grow

To further support RNA research and commercialisation efforts, a range of Australian Government grant programs are open to applications from the RNA sector. The Australian Government’s ongoing Medical Research Future Fund (MRFF) supported the development of mRNA-based vaccines and therapeutics through a specific mRNA technology enablers funding stream under the National Critical Research Infrastructure (NCRI) initiative. The NCRI initiative is delivered through open, competitive grant opportunities. The 2023 NCRI grant opportunity’s Stream 4 is focused on supporting projects that will build on, and improve, emerging mRNA technologies, platforms or equipment to accelerate development of mRNA-based vaccines and therapeutics in an area of unmet medical need.

The Cooperative Research Centres (CRC) Program supports industry-led collaborations and is a proven model for linking researchers with industry to focus on research and development towards use and commercialisation. CRC-Projects Round 12 identified mRNA as a priority with 2 successful projects starting in 2022:

- ‘mRNA manufacturing and formulation service for late stage clinical trials.’ Total project value \$7.3 million. Expected completion in 2025.
- ‘Development of an mRNA vaccine for a chronic human bacterial infection.’ Total project value \$3.2 million. Expected completion 2023.

The government has announced target investment through the National Reconstruction Fund (NRF) with: \$1.5 billion for medical science and a further \$1 billion for advanced manufacturing. The NRF will provide finance to projects (including debt and equity) in priority areas to leverage Australia’s natural and competitive strengths.

Biotechnologies are also identified as a key enabling technology field in the government’s [List of Critical Technologies in the National Interest](#).

⁸ Doherty Institute, [Doherty Institute secures landmark agreement with Moderna to expediate vaccine research for infectious diseases](#), Doherty Institute website, 24 March 2022, accessed 15 December 2022

⁹ Burnet Institute, [Burnet Institute partners with Moderna to develop novel mRNA vaccines](#), Burnet Institute website, 18 May 2022, accessed 15 December 2022

¹⁰ University of Queensland, [UQ partners with Moderna to use mRNA technology to research global public health threats](#), UQ website, 10 March 2022, accessed 15 December 2022

¹¹ Moderna, [Moderna Australian Fellowships](#), Moderna website, n.d., accessed 27 March 2023

There is also an opportunity – and shared responsibility – for government, academia and industry to encourage more collaboration and partnerships. Partnerships across Australia and with international partners to build Australian IP and capability in research, development and production of RNA vaccines and therapeutics will be important. The Australia–India Strategic Research Fund (AISRF) is an example of existing support to deepen engagement between ecosystems. Priority research areas for collaboration are based on our mutual priorities and set jointly by the Indian and Australian governments for each funding round. RNA vaccines and therapies was identified as a priority area in AISRF Round 15 (2023).

State and territory government investments are further boosting RNA development in Australia

The states and territories play a vital role in supporting RNA technology adoption and development in their existing life sciences, medical and biotechnology sectors. They have:

- developed policy and support for biotechnology and medical products
- invested in workforce development
- established collaborative precincts and networks with industry partners ranging from SMEs to larger companies.

These activities are driving the expansion of the Australian RNA sector and are attracting private and international investment.

Victoria

The Victorian Government has attracted two leading mRNA manufacturers and biotech innovators to set up manufacturing facilities, regional headquarters and research and development centres in Victoria through:

- the partnership with the Australian Government to establish Moderna’s onshore mRNA vaccine facility, with the capacity to produce up to 100 million life-saving doses of vaccines per year for respiratory diseases. This partnership is also supporting the creation of research partnerships and fellowships with Victorian medical research institutes, attracting global talent and improving local research and workforce training capabilities
- the in-principle partnership with BioNTech to set up an Asia-Pacific clinical scale mRNA manufacturing facility in Melbourne, a pre-clinical research grade mRNA manufacturing facility, an mRNA Innovation and Drug Development Centre, and an early warning system for disease identification. This partnership will deliver next-generation mRNA therapeutics and vaccines for research and clinical trials, including for infectious diseases, cancer medicines and personalised cancer treatments.

The Victorian Government has also made significant investments towards advancing RNA-based therapeutic research and development. This includes a total of \$26 million in research grant program funding across 42 mRNA medical research projects in a range of diseases including cancer, liver disease and Alzheimer’s, accelerating the attraction of global investment and new clinical trials.

The Victorian Government has also funded the establishment of the Monash Centre for Advanced mRNA Medicines Manufacturing and Workforce Training. This funding is supporting training of a skilled workforce for the local and international mRNA ecosystem, including Moderna, BioNTech, CSL and other local and global industry players.

The Victorian Government is leveraging the strengths of the Victorian biotech, research and pharmaceutical manufacturing sectors to create an attractive investment environment for the mRNA ecosystem. This includes:

- entering into formal international partnerships with the Korean Health Industry Development Institute, the Department of Health in Abu Dhabi, and with both the South African Medical Research Council and Afrigen Biologics & Vaccines, as well as significant engagement with the extensive biotech and medical research ecosystem across Australia
- a partnership with Pfizer to deliver industry fellowships for early career mRNA researchers.

New South Wales (NSW)

The NSW Government is building on previous initiatives to support high-quality, innovative research and availability of facilities, such as co-investment in the Biologics Innovation Facility (BIF)¹² at the University of Technology Sydney (UTS). This facility supports a range of university-accredited graduate programs in Good Manufacturing Practice (GMP) and has partnered with SeerPharma, a provider of technical compliance and Quality Assurance (QA) knowledge.¹³ UTS has also secured investment for a Vaccine and RNA Design Centre from the NSW Tech Central Infrastructure fund.

In 2022, NSW committed \$119 million over 10 years towards RNA research and development.¹⁴ It has also committed \$96 million to establish an RNA GMP Pilot Manufacturing Facility, to be built at Macquarie University and operated by Myeloid Therapeutics, a Boston-based company leading in mRNA-based immunotherapies. This facility is being set up in partnership with NSW and ACT universities and will include laboratories and pre-clinical trial spaces to help boost early-stage RNA-based drug development.¹⁵ The facility is expected to be completed and operational in 2025 and will produce mRNA, sRNA and LNP encapsulation.¹⁶

These investments are further supported by:

- NSW RNA Bioscience Alliance, a partnership across all NSW and ACT universities to collaborate with government and industry bodies
- NSW RNA Production and Research Network, with a \$15 million co-investment bringing together 4 universities plus several medical institutes and hospital-based facilities to enable an RNA community of practice in NSW/ACT
- establishment of the University of New South Wales (UNSW) RNA Institute through a \$25 million investment to serve as a pre-clinical manufacturing hub and deliver expertise in RNA production and formulation
- the NSW RNA Future Leaders Program, giving \$2.9 million to early-mid career researchers in RNA diagnostics, therapeutics and vaccines to support emerging research leaders.

The NSW Government has announced it is investing in development of mRNA vaccines for emergency animal diseases such as lumpy skin disease and foot-and-mouth disease. This investment is with Tiba Biotech (also Boston-based) who bring novel dendrimer nanoparticle technology and self-amplifying mRNA capability. The Queensland Government and Meat and Livestock Australia are

¹² University of Technology Sydney, [Biologics Innovation Facility](#), UTS Website, n.d., accessed 4 April 2023

¹³ University of Technology Sydney, [Good Manufacturing Practice courses](#), UTS website, n.d., accessed 1 August 2023

¹⁴ NSW Chief Scientist and Engineer, [Budget Investment to Accelerate RNA R&D](#), NSW Government website, 10 June 2022, accessed 4 April 2023

¹⁵ NSW Department of Premier and Cabinet, [New \\$96 million RNA pilot manufacturing facility for NSW](#), NSW Government website, 21 October 2021, accessed 4 April 2023

¹⁶ Health Infrastructure, [RNA Research and Pilot Manufacturing Facility](#), NSW Government website, n.d., accessed 1 August 2023

also supporting this effort, with funding now at \$14 million.

Queensland

On 5 December 2022, the Queensland Government announced a \$280 million partnership with Sanofi, UQ and Griffith University to establish a Translational Science Hub to place Queensland at the forefront of mRNA technology and vaccine development in Australia. The Hub will involve R&D to optimise Sanofi's mRNA platform and the commercialisation of an mRNA vaccine for chlamydia. The Hub allows Queensland's scientists to work closely with their peers in the Sanofi mRNA Centre of Excellence in France and the United States to accelerate a new era of vaccine technology to prevent disease. Attracting the R&D function of a major pharmaceutical company of Sanofi's standing provides Queensland with a scarce and rare opportunity. The unique experience in commercialisation provided by Sanofi will result in a local capability uplift to increase Queensland's attractiveness to other companies and potentially generate a pipeline of start-up companies. The Hub is located at the Translational Research Institute (TRI) in Brisbane and will relocate to the Translational Manufacturing facility at TRI (TM@TRI) upon completion of the facility.

On 8 June 2023, the Queensland Government signed a Statement of Intent with Sanofi regarding the establishment of a Clinical Trial Material (CTM) production unit in Queensland capable of manufacturing small-scale batches of clinical grade mRNA product for use in clinical trials. This has the potential to further vaccine and therapeutic product development, deliver added domestic sovereign capability and accelerate delivery of vaccines to patients in Queensland and Australia.

Other key Queensland-based organisations include:

- Vaxxas – with support from government, in June 2023, Vaxxas officially opened its state-of-the-art facility at Northshore Hamilton which will develop and manufacture its revolutionary needle-free vaccine technology in Queensland. Vaxxas has conducted Phase I trials in seasonal flu and COVID-19, including for a mRNA COVID-19 vaccine.
- Southern RNA – a biotechnology company focused on the development of RNA-based therapeutics. Its niche is the manufacture of mRNA and supply of raw materials (Plasmid DNA, Cap Analogues) supporting translational and clinical development activities.
- Prorenata Biotech – company focused on accelerating the development and transition of gene-based therapeutics and vaccines to the clinic. Its expertise are in CRISPR,¹⁷ LNP and genetic medicine.
- BASE Facility – builds mRNA vaccines and therapies, and hosts state-of-the-art equipment and bioprocessing technologies, with a team of skilled and experienced scientists to provide mRNA services. Services include project and mRNA design, small to large scale manufacture, formulation and expression validation.

South Australia (SA)

The Australian Government has supported BioCina with \$5 million in funding through the MRFF for development of mRNA manufacturing at clinical trial scale, as well as collaboration with industry and academic partners, Cytiva and the University of Adelaide's development of precision manufacturing processes and capabilities for RNA. The SA Government has matched this investment. BioCina is also investing to deliver full commercial Contract Development and Manufacturing Organisation

¹⁷ Clustered Regulatory Interspaced Short Palindromic Repeats

(CDMO)¹⁸ RNA manufacturing (including at population scales), under its established global regulatory approvals.¹⁹

In addition, the SA Government has invested in the establishment of an innovation intermediary in the health and medtech ecosystem to drive greater research and industry collaboration, increase knowledge transfer, attract investment and expand technology capability. This intermediary function is delivered locally by MTPConnect.

MTPConnect's local footprint in SA is complemented and enhanced by being part of a national organisation. This allows for rapid insights sharing and strategic connections within a national context. Through their national network, over 30 local stakeholders in the RNA ecosystem met with the existing and emerging nodes across the country. This helped build strategic connections locally and nationally and led to creation of new opportunities for collaboration.

MTPConnect is also delivering the Industry Doctoral Training Centre (IDTC)²⁰ for Biomanufacturing PhD+ Program. Under this program PhD students have been placed at both BioCina and CSL. The program aims to develop future research and innovation leaders that have extensive research expertise in biomanufacturing, leadership skills and a comprehensive understanding of industry. Examples of sessions, which are delivered to the PhD students and their academic and industry supervisors have included:

- Cytiva presenting on global biomanufacturing trends
- BioCina providing access to its facilities
- BioCina delivering presentations on biomanufacturing product and process development and career pathways.

Western Australia (WA)

The WA Government is supporting development of the health and medical life sciences sector through a range of measures, including the Future Health Research and Innovation (FHRI) Fund. The FHRI Fund comprises \$1.8 billion in funding to drive health and medical research, innovation and commercialisation in the state. The WA government's investment in the WA Life Sciences Innovation Hub, a partnership with the University of Western Australia (UWA) and MTPConnect, seeks to accelerate the growth of the state's medical technologies, biotechnologies and pharmaceuticals sector, create new jobs and support economic diversification.

A consortium has been formed to investigate establishment of an RNA production facility for manufacturing RNA therapeutics for cancer. The facility will be the WA-node for the RNA Therapeutics Network in collaboration with the University of Queensland (UQ) RNA production facility in Queensland. The consortium includes the University of WA, Therapeutic Innovation Australia, Harry Perkins Institute, Telethon Kids Institute, Curtin University, Cancer Council of WA and Cytiva.

The WA government has recognised the potential to build further on the state's strong capacity in cancer and rare disease precision health treatment and innovation. The WA ecosystem includes medical research institutes and biotechnology companies with specialist areas of expertise relevant to the development and manufacturing of RNA therapeutics. These organisations include:

¹⁸ Contract development and manufacturing organisation

¹⁹ BioCina, [BioCina awarded Grants to develop enabling technologies for manufacture of precision mRNA vaccines](#), BioCina website, 27 April 2023, accessed 1 August 2023

²⁰ Department for Industry, Innovation and Science, [Industry Doctoral Training Centres](#), DIIS website, n.d., accessed 4 April 2023

- the Australian National Phenome Centre, based at Murdoch University, which is the international centre of expertise in metabolic phenotyping and provides an important new platform for research across the full spectrum of health, food and the environment.
- Genomics WA, which aims to build critical mass in genomics expertise in WA by providing competitive genomics services with experts based in Perth.
- the Perron Institute for Neurological and Translational Research, which conducts specialist research within oligonucleotides to create precision treatments for a number of rare diseases. The Perron's Precision Nucleic Acid Therapeutics (PNAT) research is focused on developing novel nucleic acids therapeutic and diagnostic technologies. These technologies are designed for the treatment of various inherited/genetic and acquired diseases with the hope of helping communities improve their quality of life and provide enhanced knowledge and innovation in the scientific industry. Research is categorised into the thematic areas of:
 - nucleic acid drug synthesis chemistries
 - therapeutic and diagnostic development
 - drug delivery.
- SynGenis is supporting diagnostic and therapeutic development for both research organisations and businesses including those operating in the pharmaceutical industry. SynGenis has collective expertise in nucleic acid synthesis chemistry and experience in oligonucleotide manufacturing, leveraging the best global expertise to supply high quality oligonucleotides. SynGenis is Australia's only commercial manufacturing facility for custom synthetic oligonucleotides.
- ProGenis Pharmaceuticals is a recently launched company that develops next generation RNA therapeutics. These include splice switching antisense oligonucleotide drugs that are more efficient, safer and accessible to treat inherited rare and acquired diseases. ProGenis is led by world-renowned experts with significant experience in RNA therapeutics including in antisense oligonucleotide chemistries and manufacturing.
- Linear Clinical Research has specialist capacity in Phase I and early Phase II clinical trials, particularly trials for oncology treatments.
- the Centre for Molecular Medicine and Innovative Therapeutics, based out of Murdoch University, with world-leading researchers in the development of novel drugs for the treatment of Duchenne muscular dystrophy and other diseases.
- the Ray and Bill Dobney Cell and Tissue Therapies WA (CTTWA) facility at Royal Perth Hospital, a clinical service facility and advanced therapies manufacturing centre of excellence. CTTWA is WA's only public Therapeutic Goods Administration (TGA)-licensed manufacturer of clinical grade cellular therapies.

The megatrends that define the coming decades mean RNA will continue to grow

The COVID-19 pandemic made healthcare and biotechnology the order of the day. But even as we transition out of the pandemic, other trends are pushing RNA's growth and importance ahead. The world's population continues to grow and age, and RNA will continue to play an important role in protecting health.

CSIRO's 2022 report, *'Our Future World'*,²¹ which explores global megatrends, states that the post-pandemic world will have an escalating health imperative because of ageing population, increased chronic disease and growing antibiotic resistance. CSIRO's Infectious Disease Resilience mission²² work will inform and improve the Indo-Pacific region's ability to detect – and respond to – infectious disease threats by 2030. These will act as tailwinds to RNA's growth.

RNA sector – understanding its potential

A complex sector

RNA technology and the RNA sector are complex. It encompasses research, manufacturing and commercialisation. It sits at the intersection of pharmaceutical and vaccine manufacturing, biotechnology, medical technology improvements, R&D and commercialisation across multiple disciplines. The Australian RNA sector operates in complex global supply chains and markets.

mRNA vaccines are a good example of the complexity and systemic hurdles to taking an RNA therapeutic from initial discovery to application. They were developed after decades of work in research, engineering and manufacturing across many scientific fields, with steps including:

- initial conceptualisation and demonstration of mRNA as a functional therapeutic
- further foundational research explored the essential features, structure, and function of mRNA
- new technology developed to allow synthesis of mRNA in a lab
- RNA modification to prevent the immune system recognising therapeutic mRNA and destroying it
- LNP technology advancement allowed delivery of nucleic acids into cells
- combination of these discoveries into an end-to-end process allowed design, testing and production of mRNA therapeutics
- ramp up to mass production scale, with nanoparticles diluted, dispensed into vials and packaged similar to other medicines
- implementation to drive high uptake through accelerated regulatory pathways, system planning and application.

RNA delivery systems are key to sector growth

RNA delivery systems (the chemical mechanism that facilitates targeting RNA to cells and prevents RNA from breaking up once injected into the body) are critical to value across a range of therapeutic

²¹ C Naughtin, S Hajkowicz, E Schleiger, A Bratanova, A Cameron, T Zamin, A Dutta, [Our Future World: Global megatrends impacting the way we live over coming decades](#), CSIRO, 2022

²² CSIRO, [Infectious Disease Resilience](#), CSIRO Website, n.d., accessed 1 December 2022

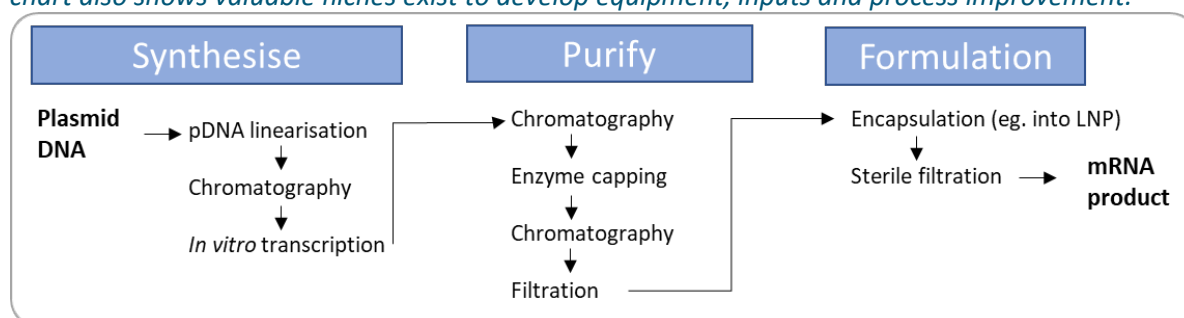
advancements in RNA science. While many researchers are capable of developing novel and targeted RNA molecules, without access to, or development of, improved delivery mechanisms for the RNA molecule, such as LNP, conversion from research to a viable product is limited.

Currently, only Pfizer/BioNTech and Moderna have approved LNP delivery systems (which are IP protected but facing multiple patent disputes²³). However, LNPs of different sizes or formulations may be needed to support delivery of future bivalent and multivalent RNA vaccines. In addition, Australian researchers are exploring the potential of other delivery systems for RNA vaccines and therapeutics, such as dendrimer nanoparticles, viral vectors, nasal sprays and needle-free patches.

Australia has a strong track record of contributions to RNA science and has capabilities and expertise throughout much of the RNA value chain. Some recent initiatives will help build more capability. State and territory government investments will further strengthen the growth of local research and industry.

At present, expertise in drug delivery systems is a critical gap, including the ability to target specific tissue types. Access to locally sourced materials and analysis services for clinical trials are important and could help accelerate technology development in Australia. Lack of LNP formulation capability beyond the NSW RNA pilot facility could be a critical limiting factor in Australia’s success and ability to advance research in the near term.

Exhibit 3: An mRNA vaccine production process. It is multi-step, needing specialised equipment and know-how to operate. While being able to produce an RNA product end-to-end is valuable, this flow chart also shows valuable niches exist to develop equipment, inputs and process improvement.



Our RNA sector operates in a broader global context

RNA is a globalised industry and taking account of global trends, value chains and the international competitive environment emerging around the next blockbuster RNA vaccines is important. Australia can have competitive niches in the greater global market, but these areas need to be identified to inform consideration of any policy or regulatory responses.

International collaboration can accelerate RNA capability

International R&D partnerships can build Australian research excellence as Australia’s small population size means it cannot specialise in everything. Collaborations will be critical to ensure Australia’s innovations are impactful and can contribute to and learn from others’ advancements.

²³ G Aquino-Jarquin, *The patent dispute over the breakthrough mRNA technology*, *Frontiers in Bioengineering and Biotechnology*, 3 November 2022, 10:1049873, doi:10.3389/fbioe.2022.1049873

Despite this, only 7% of Australia’s innovation-active businesses engage in international collaboration.²⁴

A weakly networked innovation system – domestic and international – limits the value captured from research into new and improved Australian products and services that could build competitive advantage. Complementary investments in international partnerships by both business and research institutions could help ensure sustainability of the RNA sector.

International collaboration on, and learnings from how other countries transition from emergency to steady state regulation of RNA products, will be important to ensure Australia’s future RNA vaccines and therapeutics are safe and appropriately regulated.

Access to RNA equipment and infrastructure is important for development and commercialisation

The equipment necessary to support RNA (and particularly LNP) research, commercialisation and manufacture is costly. In addition, RNA equipment also takes time to source and install.

Australian research institutions have limited equipment to support clinical trials and pilot-scale RNA. They often send DNA overseas for processing for a range of steps in RNA production because of time, availability and capability constraints. Australia is constrained by population size. The cost of modifying DNA onshore is a limiting factor for research scientists.

Clinical trial support needs GMP certified facilities after Phase I. Further clinical and commercial scale equipment – and access to it on commercial terms – could increase competition, availability of services and support greater onshore activity. Countries that secure greater RNA clinical trial activity also improve the skills, knowledge and attractiveness of their sector, growing the likelihood of more specialised activity over time.

Access to the infrastructure we do have will be critical to ensure the sector can make the most of it. It will be important for R&D facilities to meet GMP needs to expedite product approvals and commercial-scale manufacturing. CSIRO’s cGMP Biologicals Facility²⁵ is an example of the capability Australia has to support drug development and clinical trials. The facility launched in 2022 and allows the production of biologics for clinical trials (Phases I and II). It is designed and operated to be compliant with Australia’s TGA, United States Federal Drug Administration (US FDA) and European Medicines Agency (EMA) regulations. Therapeutics Innovation Australia’s Pipeline Accelerator voucher scheme is a positive example of promoting access to facilities. It encourages access to one or more of its facilities across Australia and gives up to \$50,000 (with at least 50% matched funding by applicants) to help reduce the cost of access to a specific capability for therapeutic development projects.

Our research base is strong

Our world leading universities and medical research institutes will be a major source of innovation for future RNA products. As noted earlier, Australia has a strong history in RNA, and our contributions were building blocks for mRNA vaccines in 2020. The recent investments in RNA from the Australian governments have further strengthened our research base.

²⁴ CSIRO Futures, [Value of science and technology](#), CSIRO, 2020, accessed 1 December 2022

²⁵ CSIRO, [Biologics capabilities](#), CSIRO website, 2023, accessed 28 April 2023

Some national and state-based research networks have emerged in recent years, and these are helping to improve coordination. This includes the Australian RNA Production Consortium, an informal group of RNA biomedical experts whose mission is to foster the creation of a vibrant RNA sector in Australia. As noted above, mRNA Victoria and the NSW Bioscience Alliance are adding to coordination in their states. Stakeholder feedback suggests more coordination between researchers and industry is needed.

More collaboration across state and territory borders could avoid distorting or reducing overall RNA expertise in certain areas of the country, as researchers are sought after for state-based institutions. More formal national research and industry collaboration networks could help ensure stronger national biotechnology collaborations.

In addition, academia and industry are best placed – and need to work together – to identify and focus on improving elements of RNA technology as well as prioritise which diseases RNA technology could be the best solution for. The Australian Government’s \$296 million National Industry PhD Program will support PhD candidates to do industry-focused research projects and be equipped with the knowledge and skills to better translate university research into commercialisation outcomes. On completion, candidates will have the ability to work at the interface of research and industry, and across the sectors in future.

A skilled workforce

Besides cost considerations, access to a skilled workforce is an important factor for multinational biotechnology companies when deciding where to locate their manufacturing and R&D activities. Clusters of expertise, such as those found in biotech hubs, have a competitive advantage. They offer a pool of trained and experienced workers, as well as a supportive ecosystem of related industries and service providers. This can lead to increased innovation, collaboration and knowledge transfer, further strengthening the biotech cluster and attracting more companies to the region.

Australia has a good base of skills relevant or adjacent to RNA and related technology. MTPConnect’s survey of workforce demand²⁶ found that Australia’s training institutions produce high quality skills. There is unmet demand for skilled workers with:

- commercial expertise
- regulation experience
- clinical capabilities
- knowledge in pharmacology, biopharmaceuticals and chemical sciences.

To accelerate the growth of Australia’s RNA sector, research organisations and companies need to attract, build and retain home-grown and international talent. A skilled workforce can be a determining factor in onshoring capability and R&D decisions. The Victorian Government and Monash University’s partnership to establish the Monash Centre for Advanced mRNA Medicines Manufacturing and Workforce Training is an important step in training a skilled workforce for the Australian and global mRNA ecosystems, including Moderna, BioNTech, CSL and other local and global industry players. UTS’s GMP upstream and downstream bioprocessing teaching and training is a node of the National Biologics Innovation Facility and is supported by the National Collaborative Research Infrastructure Strategy (NCRIS) and Therapeutic Innovation Australia. Both centres are, or will be, open to students across Australia and globally.

²⁶ K Borg, P Bragge, [A survey of workforce skills and capacity in the medical technology, biotechnology, pharmaceutical and digital health \(MTP\) sector](#), Monash Sustainable Development Institute, MTPConnect, 2020, accessed 1 December 2022

Stakeholders – academia and industry alike – highly value industry partnerships and fellowship opportunities because they help to accelerate capability growth along the commercialisation pathway.

Opportunities in agriculture and veterinary medicines

Agricultural and veterinary applications of RNA for livestock or companion animals represents an area of complementary Australian research specialisation that could support a unique Australian niche in RNA research and manufacturing.

Australia's large agricultural industry and high rates of companion animal ownership present a complementary sector that can build on investments made in the infrastructure and technology used for medical applications of RNA. For example, the livestock industry was valued at \$30.7 billion²⁷ in 2020–21 and is forecast to reach around \$34 billion²⁸ in 2022–23. A domestic RNA vaccine industry would offer the ability to develop vaccines specific for the animal health situation in Australia. This would also offer the opportunity to develop vaccines for exotic animal diseases in Australia and may also allow development of export markets for veterinary vaccines. This would build on a large and world-class animal health production capacity in Australia and an advanced veterinary and agricultural research community. The NSW Department of Primary Industries/Tiba Biotech consortium is active in this space and has had early success. The ability to rapidly produce vaccines at the NSW RNA Pilot facility during an epidemic of an emergency animal disease would have enormous value.

NCRIS facilities offer a flexible platform that can also support the development of testing of vaccines and treatments from animals through to humans. Ongoing assessment of whether access arrangements and the overall capacity of existing infrastructure meets the needs of a growing RNA sector may be needed.

CSIRO's Australian Centre for Disease Preparedness provides capacity to research the safety and efficacy of mRNA candidates, particularly for exotic animal diseases such as avian influenza, lumpy skin disease and African swine fever and uniquely has biocontainment level 4 facilities for large animals.

Regulation and regulatory impact in RNA technology development

The Therapeutic Goods Administration (TGA)²⁹ is responsible for evaluating, assessing and monitoring products that are defined as therapeutic goods for use in humans. The TGA does this through:

- pre-market assessment
- post-market monitoring and enforcement of standards
- licensing of Australian manufacturers
- verifying overseas manufacturers' compliance with the same standards as their Australian counterparts.

²⁷ Australian Bureau of Statistics, [Livestock disposals and products](#), ABS website, 2023, accessed 11 April 2023

²⁸ A Read, J Rollan, C Xia and F Litchfield, [Outlook for livestock](#), Department of Agriculture, Fisheries and Forestry website, 2023, accessed 11 April 2023

²⁹ Therapeutic Goods Administration, [TGA](#), TGA website, n.d., accessed 20 April 2023

Before a therapeutic good can be supplied to the Australian market, pre-market approval must be obtained from the TGA, and in most cases this involves entry of the product into the Australian Register of Therapeutic Goods (ARTG).³⁰

The TGA must be satisfied that the product meets requisite standards of quality, safety and efficacy and/or performance before approval can be given. For higher risk therapeutic goods, including those goods developed using RNA technology, this will require a rigorous scientific evaluation of data submitted by the product sponsor (applicant) and uses expertise from several fields. The TGA, like other major international pharmaceutical regulators, have adopted a range of guidelines to assist sponsors (applicants) in developing the dossier of data that would be required for regulatory purposes.

Australia is an attractive destination to conduct clinical trials. Human clinical trials that are conducted in Australia are subject to various regulatory controls to ensure the safety of participants. The TGA has published the Australian clinical trial handbook³¹ to provide guidance to clinical trial sponsors (applicants), Human Research Ethics Committees (HRECs), investigators and approving authorities (institutions).

Before an agricultural or veterinary chemical product (such as a veterinary vaccine) can be legally supplied, sold or used in Australia, it must be registered by the Australian Pesticides and Veterinary Medicines Authority (APVMA)³² or approved for use under permit.

The APVMA takes a systematic, scientific, evidence-based approach to decision making. The APVMA must be satisfied that all proposed agricultural and veterinary chemicals meet the statutory criteria for safety (including the risks of residues in food), efficacy and trade prior to registration or approval under permit. The statutory requirements for safety, efficacy and trade are the same for a permit and registration. The safety criteria used by the APVMA for chemical products,³³ including for mRNA vaccines and for an active constituent,³⁴ can be found on its website.

International regulatory collaboration – including confidence building, information sharing and work sharing – was key in the development of the mRNA COVID-19 vaccines and will continue to be for RNA therapeutics, as they may require different and additional regulatory considerations.

The Gene Technology Regulator (GTR) is an independent statutory office holder who administers the *Gene Technology Act 2000*, the object of which is to protect the health and safety of people and the environment from risks posed by gene technology. All dealings with genetically modified organisms are prohibited unless authorised. Sound science and rigorous risk analysis are central to the regulatory activities undertaken by the GTR.

Aspects of production and use of RNA technologies may be regulated under the *Gene Technology Act 2000* depending upon the activities proposed and the specific nature of the RNA. For example, where onshore manufacturing of mRNAs uses cultures of genetically modified organisms, certification of facilities and authorisation under the *Gene Technology Act 2000* would be required. The Gene Technology Regulator publishes a range of guidance³⁵, and encourages prospective

³⁰ Therapeutic Goods Administration, [Australian Register of Therapeutic Goods \(ARTG\)](#), TGA website, 2023, accessed 20 April 2023

³¹ Therapeutic Goods Administration, [Australian clinical trial handbook](#), TGA website, 2021, accessed 20 April 2023

³² Australian Pesticides and Veterinary Medicines Authority, [APVMA](#), APVMA website, 2023, accessed 20 April 2023

³³ Australian Pesticides and Veterinary Medicines Authority, [Safety criteria](#), APVMA website, 2018, accessed 20 April 2023

³⁴ Australian Pesticides and Veterinary Medicines Authority, [Active constituent](#), APVMA website, 2018, accessed 20 April 2023

³⁵ Office of the Gene Technology Regulator, [OGTR](#), ogtr.gov.au, n.d., accessed 20 April 2023

applicants or those new to the sector to contact them to discuss how they are proposing to introduce RNA technology in Australia, including import, research, manufacture or supply.

How to get involved

We want to hear your views on the high-level ideas presented in this paper. Specific responses to the overarching questions listed in the 'Questions for discussion' section are welcomed.

It is your opportunity to help us understand the challenges and opportunities to grow the RNA sector in Australia. Your feedback will help us to develop advice on the potential of our RNA sector.

To submit your feedback please do so [here](#) and also complete the survey at: consult.industry.gov.au/rnadiscussion.

If you would like to speak to us, please contact the team at onshoremrna@industry.gov.au.