## Bio-preparedness in New South Wales, Australia

#### **Diagnostics, Therapeutics and Vaccines**





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### Acknowledgement

#### NSW Government acknowledges the Traditional Custodians of the lands where we work and live.

We celebrate the diversity of Aboriginal peoples and their ongoing cultures and connections to the lands and waters of NSW. We pay our respects to Elders past, present and emerging and acknowledge the Aboriginal and Torres Strait Islander people that contributed to the development of this resource.



### Foreword from the Minister for Health

New South Wales (NSW) has an integrated, world-class health and medical research sector: we take innovations from bench to bedside every day. As Minister for Health, I am committed to ensuring the people of NSW receive world-class healthcare when and where they need it, and a strong life sciences sector is critical to this agenda. NSW is home to the largest and best performing healthcare system in Australia, and we are proud to be one of the world's finest. We have more than 220 public hospitals across metropolitan, regional, and rural parts of our state that service our culturally and genetically diverse population of over 8 million people.

Like other health systems around the world, our health system is under increasing pressure. Advances in health and medical research that provide better treatments and interventions for patients, and improved ways of delivering health services, are essential for us to provide high-quality healthcare with excellent outcomes for patients. In addition to an annual operating budget of A\$33 billion, our capital investment in health infrastructure is A\$11.9 billion over four years to 2024-25, including:

- A\$150 million to develop the Sydney Biomedical Accelerator as part of Tech Precinct
- A\$126.4 million to build one of the South-East Asia Pacific region's first GMP-grade clinical and commercial viral vector manufacturing facility
- A\$96 million towards an RNA research and pilot GMP manufacturing facility, along with \$119 million to support RNA research and development

NSW is open for business and we welcome you to join us in driving innovation and improving health outcomes.

This prospectus highlights NSW's strengths and capabilities in health and medical research, with a focus on clinical trials and biopreparedness. It emphasises the numerous opportunities for international investment and collaboration.



The Hon. Ryan John Park MP Minister for Health Minister for Regional Health

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### Foreword from the Minister for Medical Research

As Minister for Health and Medical Research I am proud of what NSW contributes to the global healthcare industry through its world-class health and medical research sector. NSW's health and medical research ecosystem is thriving and benefits from continuous and sizable NSW Government investments, world-leading experts, clinical trials infrastructure, and a focus on preparedness for approaching health threats. Our state's medical research environment is supported by expertise found in universities, medical research institutes, industry and the hospital system, all providing a strong and interconnected foundation for our health and medical research ecosystem.

The state has significant Health and Innovation Precincts, which are networked concentrations of expertise in metropolitan and regional settings and span clinical areas, support translation from bench to bench side and foster responses to emerging infectious disease.

Backed by an ecosystem that encourages multidisciplinary research, NSW-based experts are finding precision and personalised solutions to some of the world's most burdensome healthcare challenges. Our researchers are recognised globally for their achievements in cell and gene therapies, RNA, bacteriophage therapies and vaccine technologies. For example:

- The RNA Future Leaders Program is supporting world-class research to develop RNA-based therapeutics and diagnostics.
- Our researchers and clinicians are leading the world using phage therapy to treat patients with antibiotic resistant infections.
- NSW researchers are accelerating the next generation of COVID-19 vaccines with variant-proof and nasal delivery formulations.

The state is one of the top 10 destinations globally for clinical trials. We are highly competitive in providing less-expensive, world-standard trials that are fast to launch. Our large sector of research organisations is expert at managing trials for overseas companies.

I welcome you explore, partner and do business with our outstanding health and medical research sector.

Our concierge service will provide you with more information and connect you with the right partners in NSW. They can be contacted at medicalresearch.nsw.gov.au/contact-us



The Hon. David Harris MP Minister for Medical Research



# New South Wales, Australia: generating breakthroughs in healthcare

With Australia's largest population, strongest economy, and innovative life sciences sector, New South Wales (NSW) is home to an integrated, world-class health and medical research sector that is solving some of the world's most complex and burdensome healthcare challenges.

### An economic powerhouse in the Asia-Pacific region

NSW has a A\$643 billion economy, the largest in Australia and 12th largest in the world.

NSW accounts for more than half of Australia's economic growth.

The NSW economy is 50% larger than the individual economies of Singapore, Hong Kong and Malaysia and the economic and political landscape is stable and secure, with a AAA (Fitch) Credit Rating.

#### Sydney: the gateway to Australia

NSW is home to Sydney, Australia's financial centre and gateway into Australia and the Asia-Pacific.

Sydney Airport has direct services to 94 destinations in 27 countries and services 10 leading freight carriers. More than 600 multinational companies have their regional headquarters in Sydney, and many of Australia's largest venture capital firms are headquartered here.

Sydney's time zone is global, as it spans from North America late afternoon to Europe early morning and is complementary to Asian financial markets.

#### A highly skilled and diverse workforce

NSW has Australia's largest population, with 8.2 million residents. More than twothirds of the population hold post-school qualifications, and more than one third of Sydney's workforce are university qualified.

The state's population is among the most culturally and ethnically diverse in the world. English is the most widely spoken language, but almost a third of NSW residents speak a second language. NSW is home to the highest number of STEM graduates in the country and is a top ranked start-up ecosystem in the southern hemisphere. NSW is home to Australia's largest ICT industry and investment into digital infrastructure.

Australia has the fourth-highest proportion of educated immigrants in the OECD, with NSW having the highest number in Australia. Australia is ranked 9 out of 133 countries in the 2022 Global Talent Competitiveness Index.

### Personalised government support for international investors

Investment NSW centralises the NSW Government's trade and investment attraction activities, providing a single point of advice and support for the private sector.

Its role is to reinforce NSW as the most desirable place in the world to live, visit, study, invest and do business.

It acts as a concierge for business, universities, and other institutions, partnering with different parts of government and its international network to showcase what NSW has to offer and create valuable partnerships.

**Find out** what Investment NSW can do for your business: investment.nsw.gov.au



### A world-class, integrated health system



### Maximising partnerships, investment, training and research

Home to globally significant Health and Innovation Precincts: distinguished crossroads of medicine, science, education and industry.

NSW is home to networked concentrations of expertise in both metropolitan and regional areas that attract investment, generate jobs, and are excellent places to live and work.

NSW's Health and Innovation Precincts co-locate health services, laboratories, education institutes, medical research institutes and industry to maximise partnerships, investment, training and research at key NSW Health sites around the state.

These networks span clinical areas, support translation from bench to bedside and foster responses to emerging infectious diseases.

Health and Innovation Precincts provide industry partners with access to diverse patient cohorts, clinical, public health and research expertise, high-quality infrastructure and services, and the ability to drive research and development without committing to the costs of an in-house team.



### A global hub for health and medical research

The NSW Government has invested A\$10.8 billion over four years for research and development. Continuous financial investment ensures that internationally recognised research is translated into therapies and practice both locally and globally.

NSW Health has a dedicated Office for Health and Medical Research that supports research, translation and commercialisation through a range of programs:



Medical Devices Fund

which is a seed funding

43 products. Recipients

of the Fund have raised

over 311,000 patients,

approvals granted.

created additional jobs in NSW, completed more than 200 clinical trials and have had more than 70 regulatory



**Commercialisation Training** Program which develops program for new-to-world the commercialisation skills of innovators in medical medical devices. Over the past decade, the Fund has devices, diagnostics, awarded A\$78 million to therapeutics, and digital health. Graduates of the program have raised more more than A\$920 million than **A\$77 million** in private in capital funding, treated equity and grants and founded 19 start-ups.



Translational Research Grants Scheme (TRGS) which builds research capability and accelerates evidence translation within the NSW health system to improve public health. A total of A\$40 million has been awarded through six rounds of the TRGS.

A\$150 million over 10 years to build cardiovascular research capacity in NSW and make NSW a global leader in cardiovascular research.



Over A\$25 million investment in COVID-19 research to inform the NSW (and national) response to the COVID-19 pandemic, enhance research infrastructure and translate COVID-19 research findings into clinical and laboratory practice.



Health and Medical Research Concierge which is a free service to connect companies and researchers with experts, clinical networks, and research infrastructure.



### Next-generation clinical trials

NSW is a premier destination for high-quality, efficient and cost-effective clinical trials.

NSW has a reputation as a globally competitive destination for clinical trials; particularly in early-phase trials.



Governance and ethics structures enable clinical trials to start-up quickly. On average, NSW clinical trials have ethics approved and contracts signed within 90 days of application. Specialist ethics reviews of early phase trials enable approvals in just 20 days. With one third of the NSW population born overseas and up to 47 percent with at least one parent born overseas, NSW benefits from an ethnically and culturally diverse population. Clinical trials can access the entire NSW public health system with one nationally recognised ethics application.

Surveys suggest that more than half of Australian's are willing to be involved in research, including clinical trials.

A A\$30.6 million Australian Government grant under the Medical Research Future Fund supports clinical trial sites in regional and rural NSW to deliver trials, enabling access to geographically diverse populations.

NSW has a statewide Clinical Trial Management System for public hospitals and healthcare services that supports central oversight and efficient delivery.

#### Clinical Trials Connect: personalised support for clinical trials

NSW Health offers a free, personalised concierge service to stand up clinical trials in NSW through to Australia and the APAC region. Clinical Trials Connect assists industry and researchers to establish clinical trials by:

- linking trial investigators to research projects and engaging key opinion leaders
- identifying potential patient populations
- nominating contract research organisations from our large, competitive sector with specialist skills in managing domestic and international trials
- targeting clinical and industry therapeutic experts to stand up international trials
- finding specialist trial support services including clinical laboratory support, biostatistics, health economics etc.

#### Contact

clinicaltrialsNSW@health.nsw.gov.au to run a high quality, fast, and cost competitive trial in NSW.



#### **CASE STUDY**

## First in the world to treat children with gene therapy for Duchenne Muscular Dystrophy

Efficient governance processes in NSW enabled the Sydney Children's Hospitals Network (SCHN) to be the first site in an international clinical trial to dose boys between two and four years of age with gene therapy for Duchenne Muscular Dystrophy (DMD).

DMD is a rare genetic condition mostly affecting boys that causes rapid muscle loss and results in almost all patients needing a wheelchair by 12 years of age.



NSW is an experienced partner for **international paediatric** clinical trials

The DMD clinical trial is being supported by the Kids Advanced Therapeutics Program which aims to deliver clinical trials of advanced therapeutics and to speedup translation into clinical care. It is hoped that the DMD clinical trial will follow in the footsteps of other trials implemented by the SCHN and lead to better treatment options and health outcomes for the DMD patient group.

The SCHN was also the equal lead recruitment site globally, and the first site outside of North America to recruit children for an international trial of gene therapy for spinal muscular atrophy. The trial led to the first market-approved adeno-associated virus-based gene therapy drug for paediatric patients.



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### A thriving advanced therapeutics sector

NSW is an international hub for the research and development of advanced therapeutics.

NSW researchers and clinicians are recognised globally for their expertise and cutting-edge work in:



Gene and cell therapies





Bacteriophage therapies



Vaccine technologies

NSW researchers and institutions provide complete therapeutic and vaccine pipelines from design, construction and testing through to small-scale production, clinical trials and patient treatment. Cutting-edge facilities in NSW support innovative research, process development, advanced manufacturing, and delivery programs.



NSW is set to become a **major international hub** for advanced manufacturing

The NSW Government has invested in Australia's first viral vector manufacturing facility and RNA contract development and manufacturing organisation, ensuring that the state becomes a major international hub for advanced manufacturing.

The NSW Government continues to invest in workforce development, collaborative researcher, diagnostic laboratory and clinician networks, enabling infrastructure and health system readiness to fast-track access to novel therapies for our large and diverse population.



### A focus on biopreparedness

NSW Health is supporting biopreparedness alongside the state's advanced therapeutics platforms.

NSW has a strong history of investing in the generation and use of research evidence to prepare for, effectively mitigate and respond to biological threats and public health emergencies, including antimicrobial resistance and new emerging infections.



NSW has a **highly** skilled public health workforce

NSW Health supports and partners with universities, medical research institutes, consumer organisations and industry as well as large-scale, cross-jurisdictional networks to accelerate the development, commecialisation and uptake of vaccines, therapeutics and diagnostics. The highly skilled public health workforce collaborates with the research and clinical laboratory sector to ensure evidence-based decisionmaking and rapid translation and uptake of research into policy and practice.

#### **Global benefits**

This benefits NSW, but also Australia and other countries and populations around the world – NSW is connected to the World Health Organization and the Global Outbreak Alert Response Network through close laboratory, clinical and epidemiological links.

NSW Health state-wide assets that support biopreparedness include:

- a scalable, networked public health service, with workforce developed through initiatives such as the NSW Public Health Training Program
- Australia's largest public pathology and forensic provider (NSW Health Pathology) with an extensive range of research services from biomarker discovery and human and pathogen genomics through to verification, validation and utility studies
- the Centre for Health Record Linkage (CHeReL), which hosts a secure, high performing data linkage system and is one of the largest of its kind in Australia
- the newly built **NSW Biocontainment Centre** (NBC) supporting the containment, clinical and laboratory management of patients suspected of, and confirmed with, a high consequence infectious disease.



### Revolutionising diagnostics

NSW is home to internationally renowned experts who understand the intricacies of pathogens, with expertise spanning pathogens':

- ecology
- epidemiology
- genomics
- basic biology
- immune response and evasion mechanisms
- novel and molecular-based diagnostic methods
- human genetic responses.

This deep expertise allows NSW to respond quickly to public health threats by advancing diagnostics.



#### NSW was **first in the world** to publicly release the genome sequence of SARS-CoV-2



First in Australia:
to develop a PCR test
a specific SARS-CoV-2 antibody test
a validated viral culture

During the COVID-19 pandemic, NSW researchers were paramount to the rapid development of diagnostic capabilities.

NSW public laboratories provided national leadership by conducting Quality Assurance to support national PCR and rapid antigen testing, and they implemented a state-wide SMS direct-to-patient result service. NSW has also led the way in rapidly integrating SARS-CoV-2 genomics with public health responses for community safety.



NSW Health Pathology has the **only dedicated public health pathology** service in Australia.

NSW has one of the world's largest integrated Point of Care Testing program. Across NSW, over 200 regional and rural public healthcare facilities use more than 1000 handheld devices, allowing sample analysis to be performed near the patient.

NSW Health is committed to the development and commercialisation of diagnostic tools and offers a range of supportive programs. For example, the Medical Devices Fund has been highly successful in bolstering a rich and growing innovation ecosystem in the state.



#### **CASE STUDY**

### Fuelling growth and innovation in diagnostics

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The NSW Medical Devices Fund supported medical diagnostic company SpeeDx to commercialise the world's first single diagnostic test that detects sexually transmitted infections (STI) and antibiotic resistance in one.

SpeeDx has established an advanced manufacturing facility that produces a range of tests which have enabled guided therapy for over 6 million patients worldwide and driven the introduction of new STI management guidelines in Australian and internationally. In 2014 SpeeDx received A\$1.8 million for its clinical in-vitro diagnostic for viruses, bacteria, and antibiotic resistance. In 2017, it received a further A\$2.5 million to extend the ResistancePlus product line of innovative diagnostic tests.



SpeeDx now provides tests to around 60% of clinical laboratories across Australia, and NSW Health Pathology uses several of its tests. Further, the company sells tests into 17 countries, supplying some the world's largest laboratories.



### Biopreparedness through therapeutic discovery

NSW has an advanced, interconnected ecosystem supporting the development of next generation therapeutics.

#### This includes:



Gene and cell therapies



RNA therapies

Immunotherapies

Bacteriophage therapies



Plasmid-based therapies

NSW is dedicated to bringing therapies to patients faster and supports clinical trial designs that allow new therapies to be evaluated more rapidly. NSW encourages adaptive trials and is leading the global shift towards Bayesian approaches. These innovative trial designs are flexible and responsive, allowing clinicians to answer complex questions faster, personalise treatment, and to stop trials early where problems or barriers are identified.

The state's manufacturing facilities enrich our advanced therapeutics ecosystem, as well as providing Australia's tertiary training program for GMP lab staff.

The NSW Government is investing:

- \$126.4 million to build one of the Southeast Asia-Pacific region's first GMP-grade clinical and commercial viral vector manufacturing facility
- \$96 million to establish a pilot RNA therapeutics contract management and manufacturing organisation. This facility will be the first of its type in Australia and one of only a handful in the world where a range of RNA therapeutics and potential delivery technologies will be independently produced. The investment is supported by an additional \$119 million for RNA research and development.



### **RNA** Australia

RNA Australia was established in March 2023 as a joint venture and collaboration between the NSW RNA Bioscience Alliance (14 universities) and the NSW Government to lead the development of robust RNA R&D ecosystem in NSW.

#### Key objectives of RNA Australia

- **Support** the sustainable operations of the RNA Research and Pilot Manufacturing Facility towards achieving the desired commercial RNA R&D, products and services.
- **Develop** and support R&D and commercialisation of world-leading relevant technologies and therapeutics.
- Accelerate RNA R&D into new commercial products, services and expertise including delivery of vaccine.
- **Target** RNA therapies in medical applications, agriculture, biosecurity and other relevant sectors.

- Improve accessibility of advanced RNA technology therapies for humans and animals.
- **Boost** a strong network between universities, research organisations, industries, entrepreneurs and investors.
- **Foster** essential skills and pathways for innovation, R&D, manufacturing and commercialisation.

#### **Opportunities**

- Access to Open-source GMP Facility (from 2025) aimed at scaling and producing RNA therapeutics for Phase 1-3 clinical trials alongside the NSW clinical trial system.
- **Collaboration** and partnership with industry and universities including the 14 NSW and ACT universities.
- Intellectual property development with support from the RNA ecosystem.
- **Investment** in RNA developments and other related RNA activities.



#### **CASE STUDY**

### Global leadership in bacteriophage therapy: a potential solution to antimicrobial resistance

An NSW research collaboration between the Westmead Institute for Medical Research (WIMR), the University of Sydney and Westmead Hospital led by Professor Jon Iredell administered adjunctive phage therapy to 13 patients with severe Staphylococcus aureus infections.

The phages were produced under GMP conditions to ensure their quality as therapeutic products. The patients tolerated the therapy well and did not show any signs of adverse reaction from the phage therapy. This was the first time that research had demonstrated the safety and tolerability of GMP-quality IV-administered phage therapy in people with severe Staphylococcus aureus infections. In an Australian-first, clinical teams across The Children's Hospital at Westmead, in collaboration with colleagues from the Westmead Institute of Medical Research, successfully treated a seven-year-old girl using intravenous phage therapy for a longstanding bone and joint infection

The patient suffered from a severe bone infection in the leg and foot, and the initial treatment with antibiotics failed to treat the aggressive and highly resistant bacterial infection. With limited antibiotic options left, amputation was the only remaining treatment option if the infection did not resolve. NSW researchers acquired a suitable phage on compassionate grounds and administered the therapy to the patient.

After a two-week dosing regime in conjunction with long-term antibiotic treatment, the young girl's infection resolved. She did not require limb amputation, and long-term follow-up has demonstrated radiological and mobility improvement.



### Guiding vaccine research and development

#### NSW researchers are international leaders in vaccine development.

NSW researchers:

- were central to the development of the highly successful herpes zoster vaccine
- lead an international team funded by the NIH to develop the next generation of TB vaccines
- played major roles in the development of HIV treatments
- are accelerating the next generation of COVID-19 vaccines with variant-proof and nasal delivery formulations.



Bringing together the leading **vaccine, infection and immunity** researchers and practitioners in NSW

NSW is prioritising the rapid evaluation of pre-clinical vaccine candidates and novel combination vaccines targeted to regions with distinct infectious disease profiles. NSW's Vaccine, Infection and Immunity (VIIM) Collaborative Research Group informs an iterative vaccine policy for COVID-19. VIIM brings together the leading vaccine, infection and immunity researchers and practitioners in NSW. It incorporates two universities, four medical research institutes, NSW Health Pathology, adult and paediatric health services, and the National Centre for Immunisation Research and Surveillance. VIIM is well placed to support translational activities along the vaccine development pipeline, from pre-clinical development to policy and practice.

The Waratah Vaccine Trial Alliance is a onestop-shop for industry and investigators interested in conducting vaccine trials in NSW. The Alliance is a multidisciplinary collaboration of leading and emerging vaccine trial researchers, consumers and other stakeholders to support a coordinated approach to vaccine clinical trials. The Alliance will grow the next generation of clinical vaccine trialists.



#### **CASE STUDY**

#### NSW developing novel vaccines for global health

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The Centenary Institute is one of NSW's leading vaccine developers, having recently been awarded separate grants: one to develop preventive and post-exposure tuberculosis (TB) vaccines, and another to develop a mucosal, nose-only protein vaccine for SARS-CoV-2.

The US National Institutes of Health awarded a five-year grant Advancing Vaccine Adjuvant Research for Tuberculosis (AVAR-T) to The University of Sydney/Centenary Institute, and is led by Drs. Warwick Britton, Angelo Izzo and James Triccas. This project will investigate three specific antigens together with up to eight separate adjuvants, with the optimal antigen and adjuvant combination to be used as the basis for the new advanced TB vaccine that can then be taken into clinical trials. A safe and effective TB vaccine is urgently required to fight TB, one of the most significant public health problems in the world.

The Office for Health and Medical Research provided \$2 million of funding as part of

the NSW COVID-19 Vaccine Acceleration Research Grants Program, which specifically supported research projects that address an unmet need in current COVID-19 vaccines.

One of the successful recipients was Professor Warwick Britton AO, Centenary Institute, to develop a nose only Vaccine for COVID-19 – NoV for CoV. A mucosal, noseonly protein vaccine may induce protection of the upper airways to interrupt viral transmission and infection. Additionally, formulation of a subunit vaccine as a powder for nasal delivery increases vaccine equity as it is affordable, has no need for cold-chain transport so is suitable for distribution in remote or regional areas, and requires minimal community health worker support to deliver as there are no need for injections or sharps disposal.

This will further protect vulnerable groups, and reduce the disruption caused by COVID-19 to our economy and daily lives. A key partner on this project is Ab Initio Pharma which has a state-of-the-art ISO 8, Grade D manufacturing facility purpose built for the manufacture of cGMP material, with decades of experience in inhaled respiratory and nasal product development.



### Make your opportunities happen in NSW

#### **Contact us**

**For help** to access NSW Health, visit our Health and Medical Research Concierge at <u>medicalresearch.nsw.gov.au/research-concierge</u> or email <u>MOH-InternationalDesk@health.nsw.gov.au</u>

**To run** a world-class expediated and cost-effective clinical trial in NSW, visit the Clinical Trial Connect concierge service at <u>medicalresearch.nsw.gov.au/clinical-trial-connect</u> or email <u>clinicaltrialsNSW@health.nsw.gov.au</u>

**For general** information on establishing, growing and expanding your business in NSW, contact Investment NSW at <u>investment.nsw.gov.au</u> or email <u>investment.inquiries@investment.nsw.gov.au</u>

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