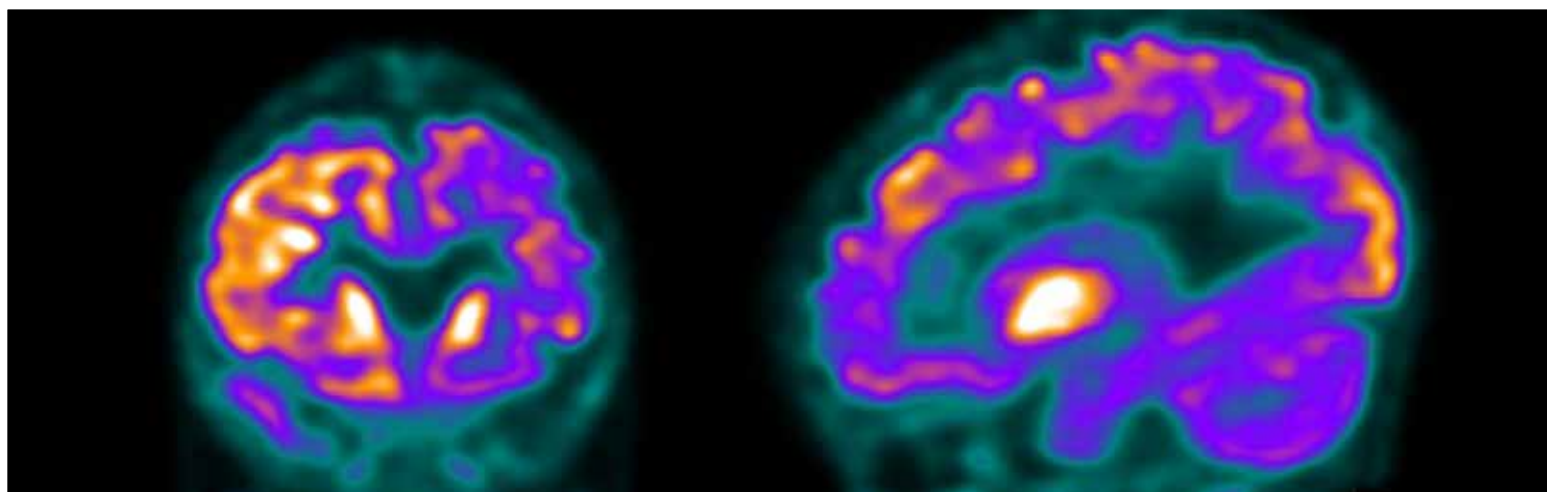




# Health Strategy



# Executive summary

ANSTO's distinct contribution to Australian health and wellbeing is through understanding and optimising the beneficial impacts of nuclear science and technology.

ANSTO is home to Australia's world leading nuclear and accelerator technologies, and combined with the expertise of our people, these are used to develop nuclear medicines and investigate the origins of disease, detection and diagnosis and therapies to improve health.

We will build on our considerable expertise in understanding, measuring and optimising radiation to benefit human health. This will become increasingly important with the introduction of new radiation therapies, such the use of micro X-rays and proton and carbon ions, which have less harmful side effects and greater effectiveness than conventional radiotherapy.

On average, one in two Australians will benefit from the nuclear medicines produced using Australia's Open Pool Australian Lightwater (OPAL) multi-purpose reactor at some point in their lifetime to aid in the accurate diagnosis of heart disease, skeletal injuries or for the diagnosis and treatment of cancer. The production of molybdenum-99, the world's most widely used radioisotope for early and accurate diagnosis of a range of diseases, is a key enabler for health. ANSTO delivers approximately 10,000 patient doses to hospitals and nuclear medicine clinics around Australia every week. The relative longevity of this isotope enables it to be safely transported to all areas of Australia and it does not need to be produced at the clinic or hospital.

Our activities will support maintaining good health by understanding the linkages between food quality and health, identifying and measuring toxic substances in our environment and unravelling the processes that contribute to the development and progression of disease.

ANSTO's capacity to produce radioactive isotopes for biomedical imaging to detect and diagnose disease will be expanded with the increased production of the most commonly used radioisotope, molybdenum-99 and the development and supply of new radioisotopes for use as tracers.

ANSTO researchers concentrate on research that can be directly applied to facilitate the development of treatments and therapies for cancers, chronic illnesses and neurodegenerative diseases among others. Our efforts will be enhanced by building on our synergistic partnerships and collaborations to drive innovation, insight and discovery.

ANSTO is in a perfect position to convene and act as a facilitator to progress matters relating to the production and supply of nuclear medicine for imaging and therapeutic use in Australia. We can build on existing collaborations and foster new relationships to gain synergistic effects and ensure all the current and future benefits of nuclear medicine are available to everyone.

The OPAL multi-purpose reactor and the Australian Synchrotron together with other significant national research infrastructure including the National Research Cyclotron Facility, the Centre for Accelerator Science, the Australian Centre for Neutron Scattering and the National Deuteration Facility, play a role in supporting Australian health.

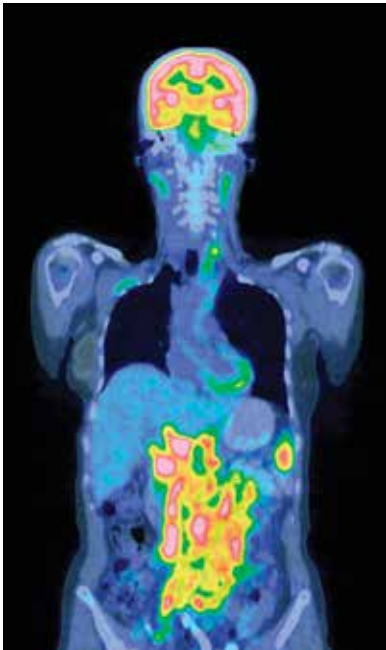
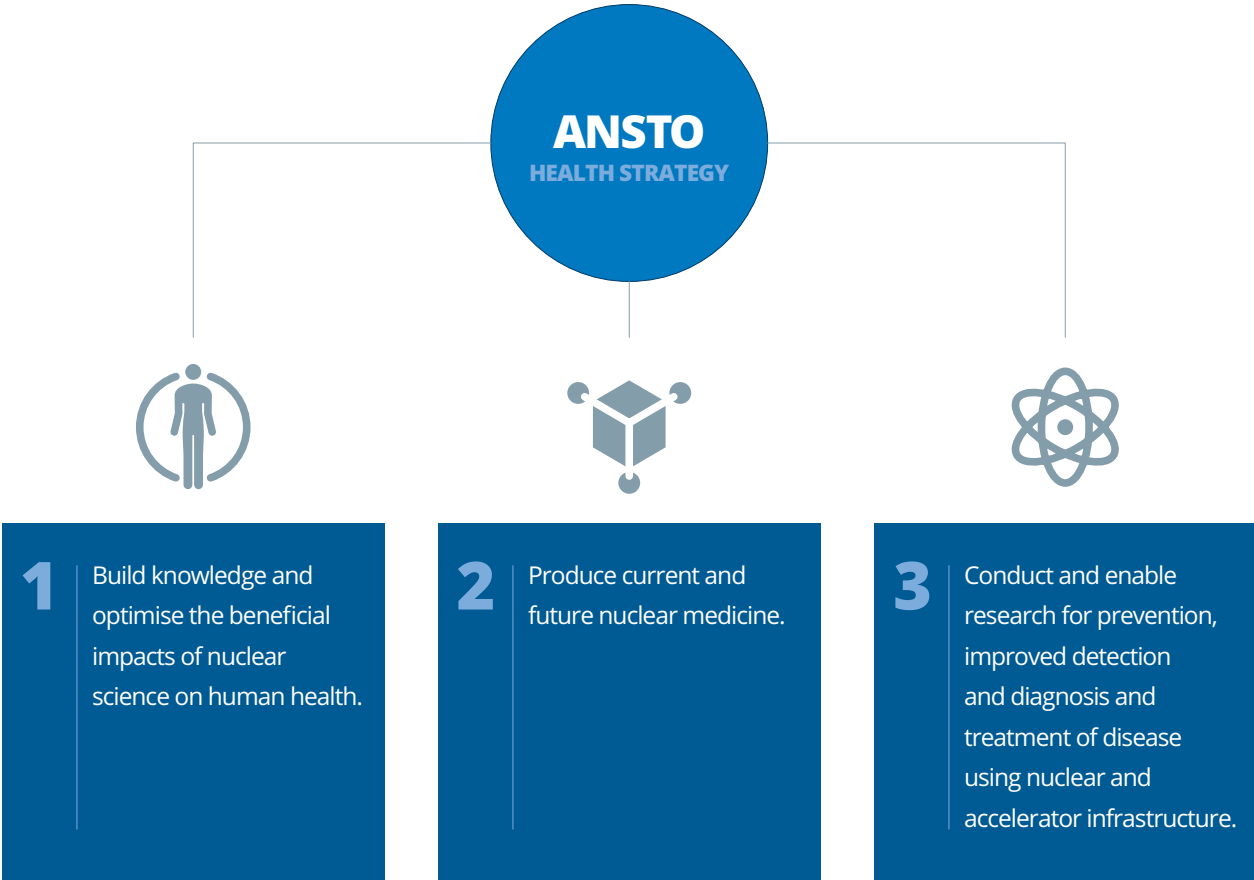
It is also important to support emerging technologies that have potential for greater human health benefits, such as particle therapy, new therapeutic radiation techniques and new therapeutic agents.

**Dr Adrian (Adi) Paterson**  
Chief Executive Officer

# Vision

A society in which all Australians experience good health.

The three key objectives of our strategy will enable ANSTO to contribute to achieving improved health outcomes for all Australians.





# Core mission

ANSTO’s health strategy is aligned with several components of its core mission as outlined in the *ANSTO Act*:

- undertake research and development in relation to the production and use of radioisotopes, and the use of isotopic techniques and nuclear radiation, for medicine, science, industry, commerce and agriculture
- encourage and facilitate the application and use of the results of such research and development
- produce, acquire, provide and sell goods, and to provide services, that are in connection with the production and use of radioisotopes, and the use of isotopic techniques and nuclear radiation, for medicine, science, industry, commerce and agriculture
- make available to other persons knowledge, expertise, equipment, facilities, resources and property

ANSTO’s activities are directed into strategic applied health research and some developmental research and commercial supply.

**Research translation** involves transferring research into clinical practice and policy to benefit human health.

**Experimental development** is systematic work, drawing on existing knowledge gained from research and / or practical experience, which is directed to producing new materials, products or devices, to installing new processes, systems and services, or to improving substantially those already produced or installed.

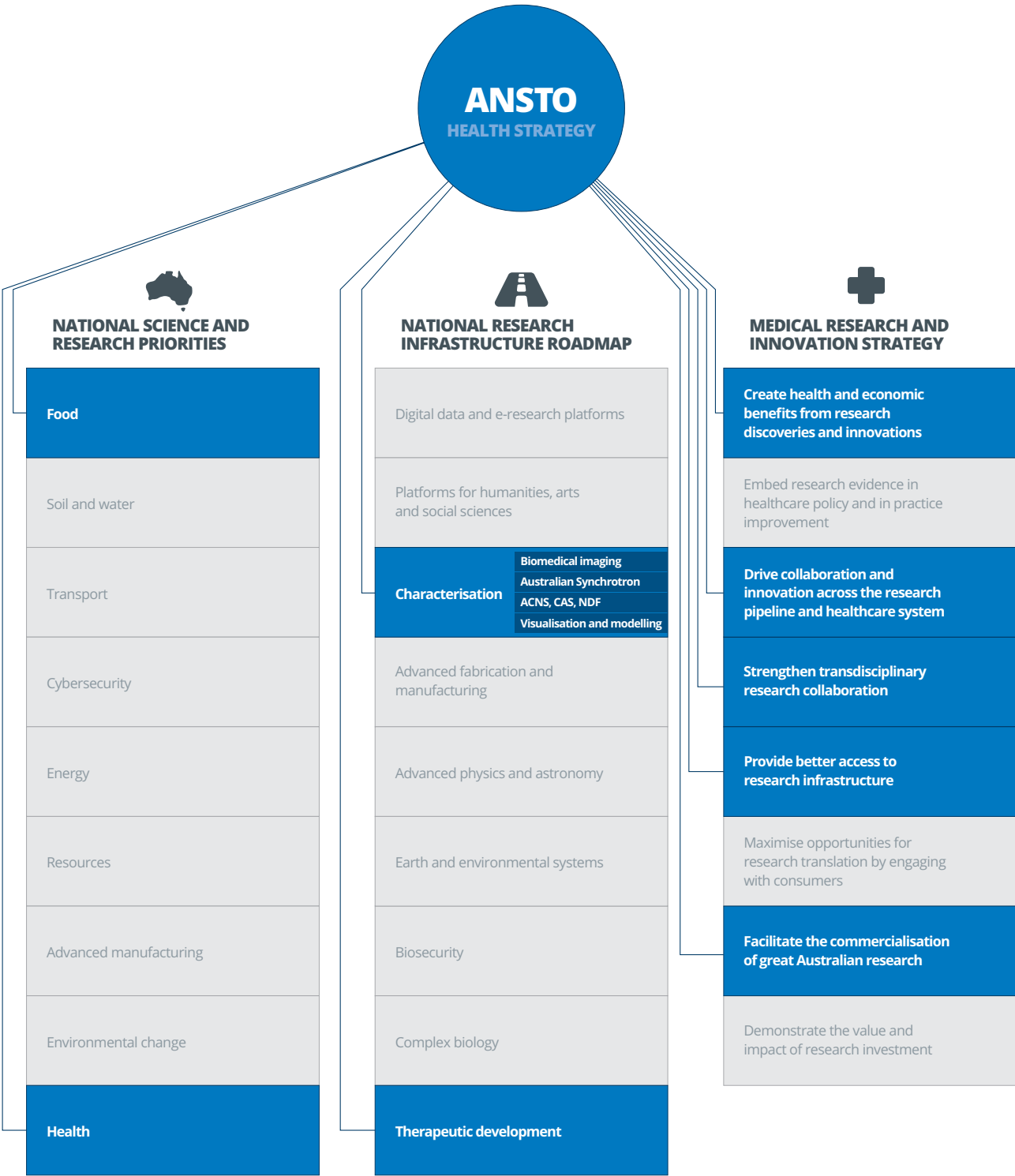


**Basic research** is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view.

**Applied research** is also original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific practical aim or objective.

# Response to Australia’s national priorities

Our strategy has been informed by the *National Science and Research Priorities*, *National Research Infrastructure Roadmap* and *Medical Research and Innovation Strategy* and areas where we have made a significant contribution and demonstrated leadership.



ACNS- Australian Centre for Neutron Scattering. CAS- Centre for Accelerator Science. NDF- National Deuteration Facility.

IN FOCUS

Responding to current health priorities

In order to give effect to the strategy, ANSTO has identified six key areas of focus where the organisation is increasing investment with partnerships and collaborations to utilise technology platforms and deliver improved services and outcomes.

ANSTO will contribute to research into the causes of and potential treatments for many chronic illnesses derived from ageing and lifestyle including diabetes, cancer and neurodegenerative illnesses which affect millions of Australians every year.

By putting people first, ANSTO is equipped and empowered to respond to the many challenges passed by current health priorities. Many of our scientists are world leaders in their respective fields.

The balance of the strategy will outline ANSTO's leadership across the areas of maintaining good health; our role in enhancing imaging to detect and diagnose disease; the development of novel treatments and therapies and driving innovation for health.

Increase ANSTO's understanding of the role of key processes that lead to the development of disease and maintenance of good health

Enhance imaging techniques to detect and diagnose disease

Undertake research to characterise and optimise the beneficial impacts of radiation on living matter

Support the development of novel treatments and therapies

Enable Australia to become a global leader in the supply of nuclear medicines

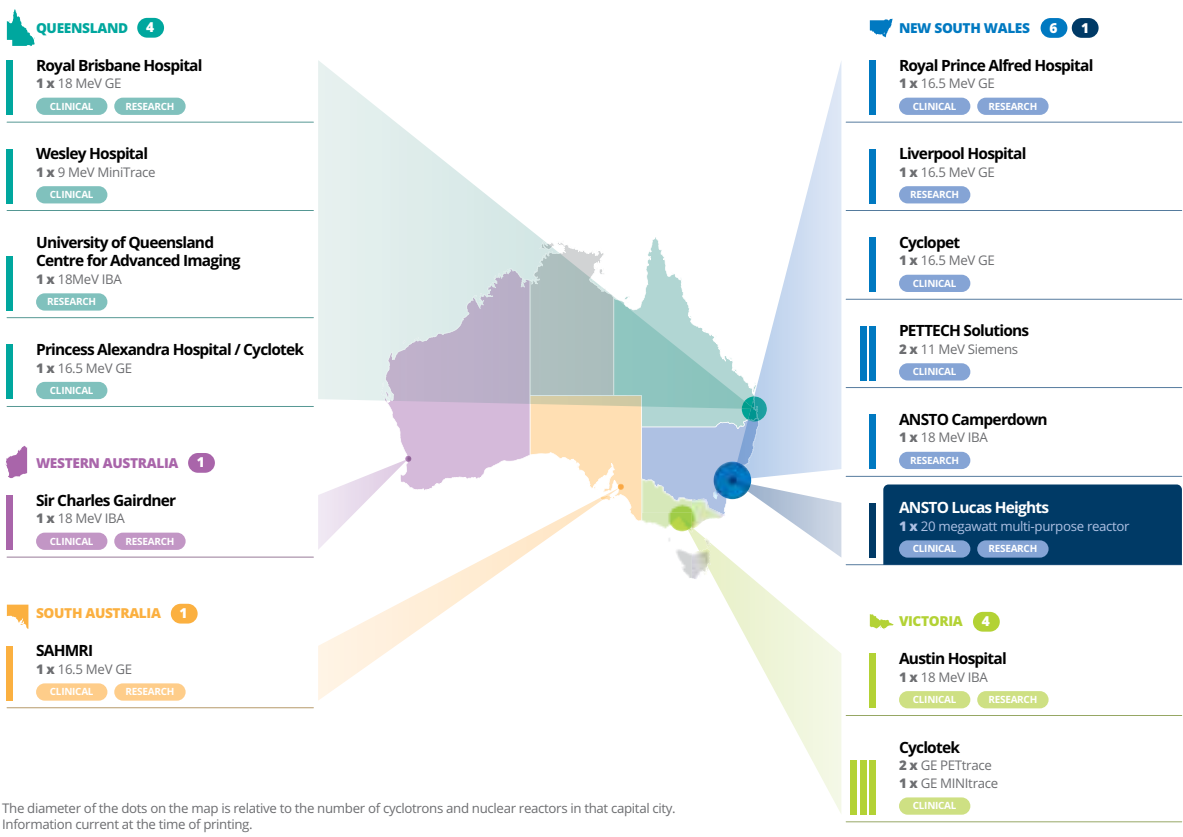
Develop and support projects that drive innovation in health

CASE STUDY

Building communities of practice to benefit Australian health

Since 2010 ANSTO has made a strategic investment in the research isotopes community to maintain and improve access to novel and new radioisotopes and collaborate on research and development.

Total cyclotrons in Australia 18  
Total nuclear reactors in Australia 1



There are **over 200 radiopharmaceuticals** that can be produced for medical research and clinical use.

Cyclotrons

Cyclotrons are used to produce a range of radioisotopes, such as:

- FLUORINE-18
- CARBON-11
- COPPER-64
- IODINE-123

Nuclear reactors

Nuclear reactors, such as OPAL, produce a range of radiopharmaceuticals and radiochemicals including:

- MOLYBDENUM-99
- LUTETIUM-177
- CHROMIUM-51

Cyclotrons around Australia produce a range of radiopharmaceuticals, such as FDG for clinical use in diagnostic imaging. ANSTO operates a cyclotron at Camperdown exclusively for the production of radioisotopes for research purposes. ANSTO's nuclear reactor, OPAL, produces a range of radioactive isotopes for research, therapeutic and commercial uses.



## ANSTO'S ROLE IN Maintaining good health

ANSTO has the capacity to address a number of global health challenges, such as the accumulation of pollutants in our environment, food production sustainability and quality and the increasing numbers of people with cancer, diabetes, and neuro-psychiatric illness.

ANSTO's research and development will look at reducing the risks which lead to population health impairment and disease. It will also harness nuclear technologies to help people maintain good health and accelerate their recovery. This will include research to assess environmental risks, such as chemical, physical and societal risks, understand their impact on health and offer strategies for early mitigation.

ANSTO undertakes research and has a suite of highly sensitive instruments able to detect very small amounts of pollutants in the air.

Each year it is anticipated that hundreds of Australians will die due in part to exposure to fine particle pollutants. ANSTO has been using accelerator techniques to analyse fine particle pollution samples collected from key sites around Australia, and internationally, for more than 30 years.

Rapid urbanisation has created a concurrent rise in fine particle pollution, generated by industry, trucks, coal-fired power stations, cars and other man-made sources. These fine particles can also cause significant health problems, as the human nose and throat are inefficient at filtering them out, meaning they can penetrate deep into the lungs and even our blood stream. This work is helping to better inform federal and state governments on air quality and the long-term changes in the levels of fine particle pollutants.

A range of nuclear imaging techniques can also be used to measure uptake of heavy metals in living systems and under laboratory conditions.

ANSTO is developing a range of techniques and methods to understand the impact of food and nutrition on human health. Food authenticity and provenance have become key concerns to industry and the public. ANSTO is working in partnership with the NSW Department of Primary Industries and the University of New South Wales to enhance the health and well-being of Australians and achieve impact on a global scale. ANSTO is contributing its unique nuclear technologies, tools and expertise to optimise food production efficacy and quality (such as enhancing fish aquaculture for human consumption). ANSTO has the expertise to track physical origin for safety and quality authentication purposes.

Enhancing food quality means optimising food production. This involves tracing and monitoring not only high value nutrients, but also pollutants and contaminants (such as heavy metals, plastics and nanoparticles). Monitoring these at key points in the food web and during various steps to delivery will enable us to understand points of contamination and therefore reduce the risks of exposure through food absorption.

ANSTO is working with a number of universities to gain knowledge and develop novel techniques to measure, predict and optimise food function and provide health outcomes for consumers and for the benefit of the economy more broadly.

Research that aims to determine the causes of disease and understand the development of disease can lead directly to prevention strategies. An example was the creation of the first healthy mouse genetically engineered without the gene responsible for a key protein that has a role in inflammation, obesity and chronic illness.

Building on our expertise, nuclear and accelerator techniques and our partnerships with research organisations, ANSTO leads research in understanding these risks and elucidate the mechanisms that underpin the progress of chronic disease from an initial response.



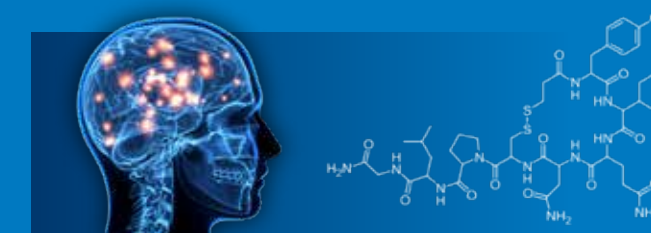
## CASE STUDIES



### Using nuclear techniques to trace microplastics

ANSTO environmental researchers are using nuclear techniques to gain insights into how pollutants, such as microplastics, are taken up by aquatic organisms. The research is expected to contribute to an understanding of how microplastics move through the food web and may ultimately be ingested by humans.

Microplastics are fragments of plastic less than five millimetres long. The quantity of microplastics in marine organisms, such as prawns, following exposure to realistic concentrations can be measured. The location of the microplastic radiotracers in the organism can be determined using autoradiographic imaging. This will inform whether the plastics have accumulated or are shed by the animal.



### Tracking the hormone oxytocin












ANSTO is participating in a \$1 million Australian Research Council project to understand how the hormone oxytocin may influence human thinking and behaviour and explain its potential usefulness as a treatment for autism and other disorders.

It is expected to lead to the development of a new oxytocin radiopharmaceutical that behaves like natural oxytocin in the body. In addition to its role in a range of physiological functions, oxytocin appears to regulate mechanisms that underlie aspects of social cognition in humans as well.

Human health researchers are applying ultra-sensitive imaging techniques using radio-labelling probes in combination with positron emission tomography (PET) to determine the pathway that oxytocin takes to reach receptors in the human brain.

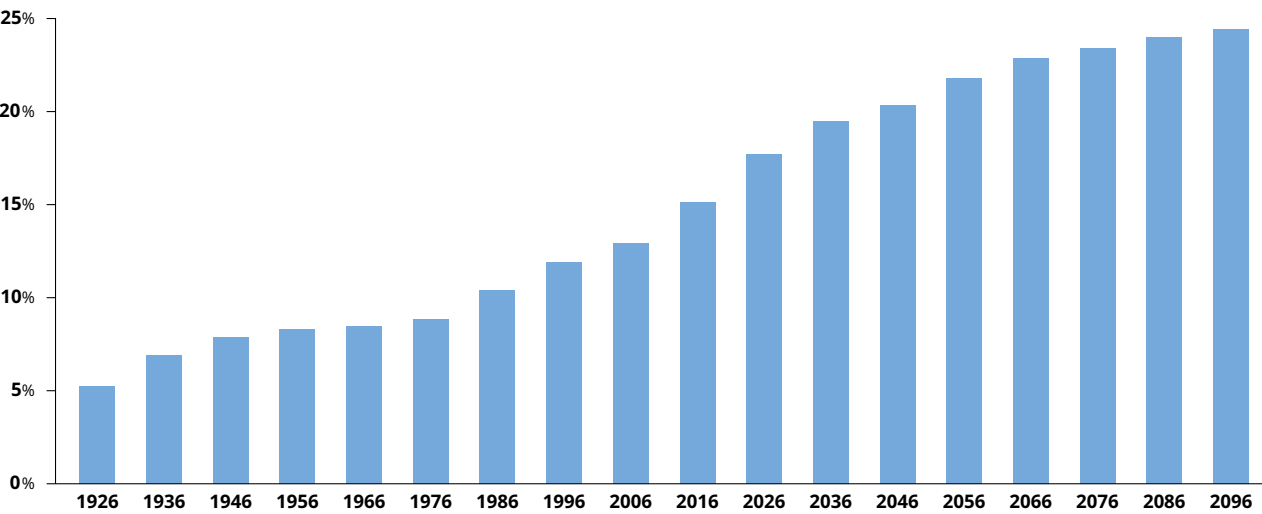


ANSTO'S ROLE IN  
Maintaining good health

| STRATEGIC GOAL   | ANSTO LEADERSHIP PROGRESSION | PARTNERSHIPS   | COLLABORATORS  | TECHNOLOGY / PLATFORM                          | PRODUCT / SERVICE                          |
|--|------------------------------|--|--|--|--|
| Undertake research and develop tools to assess food provenance, quality and production                                 | Emergent                     |    |  Department of Primary Industries   |  |  |
| Undertake research into food quality and metabolism to understand how it leads to the development of disease           | Emergent                     |    |  |  |  |
| Contribute to identifying multiple environmental factors that induce complex diseases                                  | Established                  |   |  Hôpitaux Universitaires Genève  |  |  |
|  |                              |    |  |  |  |
|  | Advanced                     |    |  | IMBL and MX beamlines (Australian Synchrotron) |  |
| Undertake research to fully understanding the impact of pollutants to reduce diseases linked to environmental exposure | Advanced                     |  |   |  | Fine particle characterisation / databases |
|  | Established                  |    |  | Biosensors to detect pollutants                |  |

Please note this list does not include all current partners and collaborators.

Australian population aged 65 and above over time



Source: Australian Bureau of Statistics.



## ANSTO'S ROLE IN

# Enhancing imaging to detect and diagnose disease

### Radiotracers and radiopharmaceuticals

Identifying and stopping disease progression during the time when there are no symptoms is now a major focus in pharmaceutical industry-based research strategies

Nuclear imaging techniques, in particular positron emission tomography (PET) and single photon emission computed tomography (SPECT), are both specific and sensitive enough to assist in early detection and assessment of small physiological changes in the body.

To help contribute to this agenda, ANSTO-led research focuses on delivering the next generation of highly flexible and better medical radiotracers that emit low levels of radiation for imaging purposes.

These radiotracers are key tools to diagnose, treat diseases, improve an assessment of the staging of disease and support the selection of the best treatment options.

The new radiotracers are associated with imaging methods that deliver ultra-low doses of radiation in the procedure.

By combining imaging methods in living subjects with other approaches, at pre-clinical and clinical stages, we will contribute to advances in personalised, diagnostic and therapeutic strategies, such as theranostics. Radiotracers can be designed to achieve the best clinical outcome for the patient.

ANSTO's research objective is to reduce patients' exposure to radiation so we will focus on developing strategies to increase the performances of radiotracers and decrease the dose delivered to the patient during PET imaging.

To achieve this, ANSTO is leading research in defining new strategies to design deuterated radiotracers that will demonstrate enhanced stability and metabolic profiles, leading to enhanced image quality and reduced radiation levels to patients.

Our approach extends to bringing new methods and products to clinical validation and ultimately to patients through partnerships and collaborations with universities and industries.

Together with international partners and the University of Sydney, ANSTO aims to bring ultra-low dose PET imaging to clinical reality. To do this our research will focus on developing methods to take advantage of the total-body imaging approach and map all relevant biological functions that will help unravelling patients' complex diseases.

The total-body imaging will become a critical tool to understand the interactions between distant organs in the progression of conditions, such as the gut-brain crosstalk in metabolic control and diabetes.

The Camperdown Precinct including the National Research Cyclotron Facility, imaging centres and co-located medical research institutes will become a major hub for translational medical research.

ANSTO offers collaborators and industry partners unique access to a complete portfolio for translation into radiopharmaceuticals, including radiochemistry expertise for radioisotope production, development and production of radiotracers, design of pre-clinical studies, and Good Manufacturing Practice (GMP) supply into clinical trials. It meets the needs of both the clinical research community and the biotechnology and pharmaceutical industries.

The portfolio represents a cornerstone of national capabilities in radiotracer imaging, diagnostic and therapeutic methods. Strategic plans include the addition of solid target capabilities to our Camperdown cyclotron to expand national capabilities and the development of new automation technologies to optimise radiotracer production.

By combining imaging methods in living subjects with other approaches we will contribute to advances in personalised, diagnostic and therapeutic strategies.

### Nuclear medicine production

ANSTO supplies approximately 80 per cent of Australia's radioactive isotopes used in nuclear medicine. More recently, ANSTO joined the global marketplace for nuclear medicine production, and has the capacity to supply 35 per cent of the global demand for molybdenum 99, the precursor to technetium 99m, which is the most widely used diagnostic imaging agent.

ANSTO will continue to support access to diagnostic and therapeutic isotopes for nuclear medical procedures in Australia and is well positioned to support this need for isotopes in the domestic market and to expand into the Asia / Pacific region.

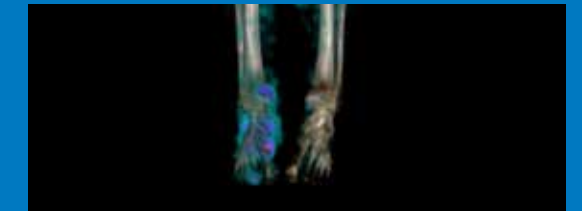
To secure long-term production, ANSTO will define a set of future requirements and a facility conceptual design. ANSTO will engage with the Australian New Zealand Society of Nuclear Medicine (ANZSNM) and industry suppliers and customers to manage supply chain — ensuring issues are mitigated.

The upscale ANSTO Molybdenum-99 Production Facility will secure both domestic and global supply well into the future.

In the coming years, ANSTO will be seeking to undertake a capital program to upgrade its nuclear medicine processing facility in order to meet current and future compliance requirements. It enables ANSTO to meet increased demand and allows for the introduction of new diagnostic and therapeutic agents.

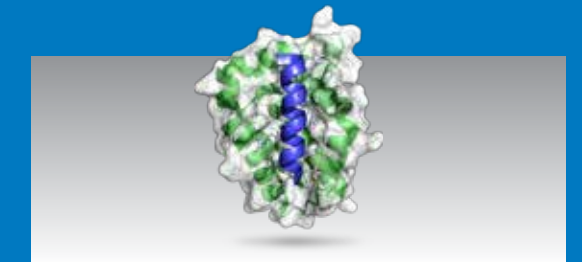
ANSTO will continue its close relationship with the nuclear medicine community to identify future products with both diagnostic and therapeutic benefits.

## CASE STUDIES



### Developing innovative cancer diagnostic agents through collaboration

ANSTO participated in an Australian biopharmaceutical collaboration led by Minomic International that developed an innovative cancer diagnostic agent, which can be used to detect and potentially monitor metastatic prostate, bladder and pancreatic cancers using SPECT/CT radiotracers. The radiolabelled antibody, known as MILGa, is currently at the Stage 1 clinical trial phase. As well as providing a means to visualise disease progression, there is potential to combine the drug with a radioisotope such as lutetium-177, that will offer improved therapeutic options for patients with difficult-to-treat cancers.



### New leukaemia drug Venetoclax

The Australian Synchrotron played a crucial role in the discovery of a successful new drug for chronic lymphocytic leukaemia (CLL) that has now received regulatory approvals for use by Australian, European and American patients.








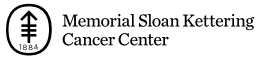







The drug, Venetoclax, is a major advance for CLL patients who don't respond adequately to currently available treatments.

The Medical Imaging (MX2) beamline was used to provide highly detailed 3D images of protein structures. The level of detail was important in developing a drug that targets a single protein and critical for minimising potential side-effects.

The research was led by researchers at the Walter and Eliza Hall Institute in partnership with two major international pharmaceutical companies.

CLL is the nation's most common leukaemia.

# ANSTO'S ROLE IN Enhancing imaging to detect and diagnose disease

| STRATEGIC GOAL   | ANSTO LEADERSHIP PROGRESSION                                | PARTNERSHIPS  | COLLABORATORS   | TECHNOLOGY / PLATFORM                  | PRODUCT / SERVICE                            |
|--|---|---|---|--|--|
| Undertake research to develop next generation radiotracers for enhanced detection of disease                           | Established<br><div><div></div><div></div><div></div></div> | <div>  MONASH University </div> <div>  National Imaging Facility </div> <div>  Berkeley </div> <div>  UNSW </div> |   | Deuteration of radiotracers            | Radiopharmaceuticals and radiochemicals      |
| Continue to support the development of advanced radiotracers for diagnosis and treatment                               | Emergent<br><div><div></div><div></div><div></div></div>    |   | <div>  minomic </div>                                |  | MILGa  |
| Undertake research to develop multi-modal radiotracers and imaging technologies  | Emergent<br><div><div></div><div></div><div></div></div>    | <div>  UTS </div> <div>  Curtin University </div>  | <div>  Memorial Sloan Kettering Cancer Center </div> |  |  |
| Provide infrastructure to enhance understanding of disease using synchrotron imaging techniques                        | Advanced<br><div><div></div><div></div><div></div></div>    | <div>  MONASH University </div> <div>Also multiple Australian Universities and other co-partners</div>  |   | IMBL beamline (Australian Synchrotron) |  |
| Undertake research to contribute to the development of advanced radiotracers for ultra low dose imaging                | Emergent<br><div><div></div><div></div><div></div></div>    | <div>  ESRF </div>   |   |  |  |
|  | Emergent<br><div><div></div><div></div><div></div></div>    | <div>  THE UNIVERSITY OF SYDNEY </div> <div>  UC DAVIS </div>  |   |  |  |
|  |   | <div>  National Imaging Facility </div>   |   |  |  |
| Provide quality control services for measuring radioactivity to safeguard therapeutic radiation detection and delivery | Advanced<br><div><div></div><div></div><div></div></div>    | <div>  IAEA </div>  |   | Radiation metrology                    | Radiation metrology services                 |
| Maintain and increase the supply of radiotracers for biomedical imaging  | Advanced<br><div><div></div><div></div><div></div></div>    |   |   |  | Molybdenum-99                                |
| Provide products for use in biomedical imaging to improve the detection and diagnosis of disease                       | Emergent<br><div><div></div><div></div><div></div></div>    | <div>  HUG </div> <div>Hôpitaux Universitaires Genève</div>   |   |  | Translocator protein (TSPO) related products |

Please note this list does not include all current partners and collaborators.



## ANSTO'S ROLE IN

# The development of novel treatments and therapies

### Theranostics

In addition to creating radiotracers for treatment optimisation and therapy follow-up, we lead research to develop multi-modal agents which combine the benefits of imaging (PET, SPECT) with 'interventional visualisation' (NIR-optical) and radiotherapeutic lutetium-177 into one agent. The same molecule being used will significantly improve the accuracy of diagnosis, simplify and fast-track treatment protocols and improve outcomes for Australian patients.



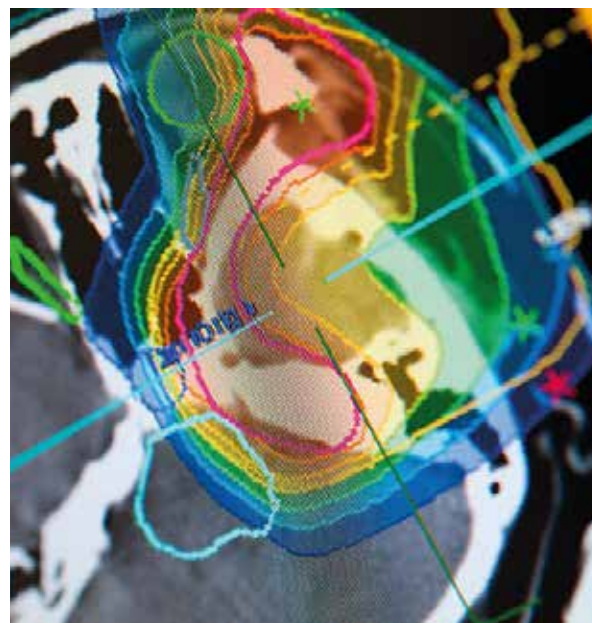
### Particle Therapy

Current treatment strategies for the majority of cancer patients include the use of external radiotherapy, either exclusively or in combination with other treatments. Our goal is to optimise radiation delivery by maximising the radiation dose delivered to the target volume while minimising the dose delivered to other regions.

This can also be achieved by quantifying biological response of different tissue types (tumour and normal) with respect to particle characteristics and delivery protocols. This will lead to combined treatment schemes that improve patient recovery.

In partnership with the University of Wollongong and international partners, our research will focus on developing detection instruments, accurate simulation and analytic models for the physics of fragmentation in proton and heavy ion particle therapy. This research will produce innovative new techniques including image-based spatial dosimetry verification and dose enhancement.

The knowledge generated associated with new methods and innovative protocols will allow us to understand how ions interact with matter, how we can measure the exact delivered dose and how we can enhance and optimise the impact on the disease progression.



### X-ray technologies

The Australian Synchrotron plays a pivotal role in developing and operating critical research infrastructure that supports health-based research undertaken by Australian and international researchers.

The Imaging and Medical Beamline (IMBL) has two central capabilities that relate to health research: Microbeam Radiation Therapy (MRT), and Biomedical Imaging. MRT is an experimental form of cancer therapy being developed at the Australian Synchrotron, with staff working alongside researchers from Australia and Europe. Current efforts relate to investigating the mechanisms that underpin this technique as well as proving its efficacy on experimental model.

As the regulator of radiation safety, ARPANSA works with the team on the IMBL, developing new dosimetry (measurement) capabilities to support future programs in which human subjects will be imaged and potentially treated with MRT.

Partnerships with Australian and New Zealand universities, medical research institutes, hospitals and other research institutions will further expand the number of beamlines available for imaging health, including dedicated high performance macromolecular crystallography and small-angle scattering for analysis of proteins in solution.



### New therapeutic agents

An increase in the production of new radioisotopes, such as lutetium-177 for therapeutic application, positions ANSTO as a key supplier in this emerging market. Infrastructure was added to the OPAL reactor to produce lutetium-177 for local clinical trials and compassionate use of this new drug.

The OPAL reactor has the technical design basis to support the production of a range of other therapeutic radioisotopes, such as scandium-47, that will be new to Australia. Pairing reactor radioisotopes with those produced by cyclotrons using solid targets provides powerful diagnostic and therapeutic tools.

One such theranostic combination, which tailors treatment to the patient, is gallium-68 with lutetium-177. Through collaborations with other cyclotron centres having solid target capabilities, in particular Austin Health (VIC) and Sir Charles Gairdner Hospital (WA), ANSTO has access to clinically important radioisotopes such as copper-64, iodine-124 and zirconium-89.

The high reliability of OPAL, access to unique isotope production facilities at ANSTO Lucas Heights and employment of the Australian cyclotron network establishes Australia's leading production capability and ensures that there is a strong supply chain for clinical translation studies throughout the country.

ANSTO is now a supplier of lutetium-177 in Australia (supplied under a special access scheme of the Therapeutic Goods Administration (TGA) for clinical trials and specific patients), and is ideally placed to support this growing therapeutic opportunity. Lutetium therapy has been included in the Clinical Oncological Society of Australia (COSA) guidelines as a standard treatment option in Australia for advanced neuroendocrine tumours (NETs). In addition, new data suggests lutetium-177 labelled with prostate-specific membrane antigen (LuPSMA), being trialled for late stage prostate cancer, is promising. Local studies in Australia have already commenced with the support from ANSTO.



## ANSTO'S ROLE IN

# The development of novel treatments and therapies

### Molecular labelling for new products and services

ANSTO's National Deuteration Facility offers capabilities unique in the Southern Hemisphere, producing new research tools and products relevant to patient health. Labelling biomolecules with deuterium instead of hydrogen enables them to be studied using neutron scattering techniques at ANSTO for cutting-edge applications. This includes investigation of the relationship between molecular structure and functions, enabling investigations of how toxins enter cells, how drug targets interact with receptors and how proteins interact — throwing light on degenerative disease causation and informing infectious disease vaccine design.

Biodeuteration is useful to researchers and industry during many research stages of investigation and can be used to assist in the study of proteins, biopolymers, and biomembranes.

ANSTO is particularly well placed to take advantage of the latest trend in pharmaceutical design occurring in the USA and Europe where companies are now demonstrating and registering deuterated pharmaceuticals that provide lower effective dose concentrations and fewer side effects than their conventional counterparts.



### Stewardship

ANSTO maintains Australia's primary and secondary standards for the activity of certain radionuclides on behalf of Australia's Chief Metrologist. This capability contributes to improved patient health outcomes and is crucial in ensuring the accuracy and reliability of doses of nuclear medicine being delivered to patients.

Benefits to the nuclear medicine community are delivered via ANSTO's Australian Nuclear Medicine Traceability Program (ANMTP) and Australian Industry Becquerel Traceability Program (AIBTP).

The ANMTP provides nuclear medicine services to hospitals and practices around Australia with measurement traceability to the national standard of radioactivity, ensuring hospital and Australian nuclear medicine industries equipment is properly calibrated to the standard.

The AIBTP provides traceability to the Australian standard of radioactivity for key commercial radionuclide products including technetium-99m, molybdenum-99, iodine-131, lutetium-177 and fluorine-18, and delivers services to specialist commercial pharmacies around Australia. This program aids the provision of correct radiopharmaceutical activities to nuclear medicine practices and assists with compliance with legislative trade measurement regulations.


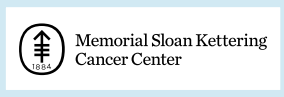














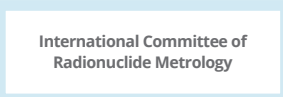

Stewardship activities and services are being expanded to provide traceability measurements for novel and emerging radiopharmaceuticals.





# ANSTO'S ROLE IN

## The development of novel treatments and stewardship in the use of radiation

| STRATEGIC GOAL  | ANSTO LEADERSHIP PROGRESSION | PARTNERSHIPS  | COLLABORATORS  | TECHNOLOGY / PLATFORM  | PRODUCT / SERVICE                            |
|---|------------------------------|---|--|--|--|
| Undertake research to contribute to the development of advanced radiotracers for diagnosis and therapeutic treatment (theranostics) | Advanced                     | <div>  </div>   | <div>  </div>   |  | Deuterated molecules                         |
|   | Emergent                     | <div>  </div>   | <div>  </div>   |  | SARTATE™ †                                   |
|   | Established                  |   |  |  | Lutetium-177                                 |
|   | Emergent                     | <div>   <div>  </div> </div>   |  | MX2 beamline<br>(Australian Synchrotron)                                       | VENCLEXTA™ †                                 |
| Enhance infrastructure to advance the development of new and improved treatments for disease  | Emergent                     | <div>  </div>   |  | Proposed new beamlines: BIOSAX, MCT, XAS, HCN, MMC<br>(Australian Synchrotron) |  |
|   | Advanced                     |   |  |  | Translocator protein (TSPO) related products |
| Undertake research on advanced radiation therapy  | Emergent                     |   | <div>   </div> | Therapies using protons, carbon and other heavy ions                           |  |
| Undertake research to fully characterise the impact of radiation on living matter   | Advanced                     | <div>   </div>   | <div>  </div>   |  | Radiation dose detectors                     |
| Provide quality control services for measuring radioactivity to steward the use of therapeutic radiation                            | Advanced                     | <div>   </div> <div>   </div> |  |  | Becquerel traceability program               |
|   | Emergent                     | <div>  </div>   |  | New dosimetry capabilities for new beamlines<br>(Australian Synchrotron)       |  |

Please note this list does not include all current partners and collaborators.  
† Product provided by partner.

## ANSTO'S ROLE IN Driving innovation for health

### National Particle Treatment and Research Centre

Particle therapy is a cutting-edge treatment that destroys cancer non-invasively using charged ions. Particle therapy offers advantages in treatment efficacy over conventional radiotherapy using X-rays. It allows clinicians to target cancers more effectively, reducing radiation doses to healthy surrounding tissues and reducing the number of treatments required.

The Australian Government's welcomed investment in Australia's first particle therapy facility, at the South Australian Health and Medical Research Institute, will assist the South Australian Government in delivering the most mature form of particle therapy, which uses proton beams, for the first time in Australia. Proton-based particle therapy is a well understood and well utilised technology that was first trailed internationally in the 1950s. There are now more than 60 proton facilities internationally, and a further 40 under construction as of July 2017. Proton-based particle therapy in Australia will allow Australian clinicians to deliver effective treatments to a cohort of patients who would otherwise receive sub-optimal care.

Particle therapy is not restricted to the use of protons. Carbon ion-based particle therapy is an emerging technology being applied in Japan, Germany, Austria, Italy and China. It is proving to be effective against some cancers for which there is currently no treatment. Its deployment would significantly improve patient outcomes and take Australia into a community of nations adopting the most advanced approach to cancer treatment.

ANSTO is facilitating a national discussion on Australia's approach to particle therapy that encompasses the well-established proton-based technologies, and the emerging carbon ion-based technologies. It is also providing technical assistance and access to overseas experts through its international networks to the various state-based proposals that are being developed. In particular, ANSTO has assisted the NSW Government in developing the only proposal to date that would deliver a carbon ion particle therapy facility, at the Westmead medical precinct in Western Sydney.

### eResearch

The emerging research programs and infrastructure that underpins the ANSTO Health Strategy are supported by an eResearch or digital infrastructure plan. The diversity of health research and related techniques require a range of digital systems including high performance computing, data storage, visualisation and data analysis tools. The capacity of these systems is influenced by state-of-the-art infrastructure that generates large-scale, multi-modality data sets as well as the needs of researchers working in distributed teams requiring in-house and cloud-based collaboration tools

### Accelerator based technologies

Continuing collaboration and partnership with the European Organisation for Nuclear Research (CERN), internationally, and local industry, domestically, strengthens ANSTO's role in the development of accelerator technology, the next generation of world-class particle accelerators.

Recent advances in accelerator and laser technologies offer the potential for vastly more powerful compact X-ray light sources for imaging and other techniques at a cost that most modern laboratories and hospitals can afford.

The Australian Synchrotron will continue to focus on the implementation of more compact accelerating structures, such as compact light sources that offer synchrotron bend magnet performance from a room-sized laboratory. This approach is at the forefront of disruptive technology, and has significant potential application in research and clinical settings.



### ANSTO Innovation Precinct

In line with the national priority to drive Australian innovation through greater synergies between science and business, as articulated in the *National Science and Innovation Agenda (NISA)* and *Australia's National Science Statement 2017*, ANSTO is developing a proposal to establish an Innovation Precinct at its main campus in Southern Sydney. The ANSTO Innovation Precinct will have three major components; a Graduate Institute, an Innovation Incubator and a Technology Park. It will 'crowd in' and co-locate knowledge-intensive businesses, high-tech industry, science, technology, engineering, mathematics and medicine (STEMM) graduates from Australian universities, and scientific partners around Australia's centre of nuclear capabilities and expertise. This will create an innovation community that nurtures and drives technology development and transfer, commercialisation, entrepreneurialism, collaboration and market-ready postgraduates.

### Intellectual Property (IP)

ANSTO is committed to securing IP over concepts, processes, products and technologies which we lead. We will develop our intellectual property and commercial capabilities as a strategic asset for the Australian Government and to strengthen our financial performance in order to better support our research programs, infrastructure and services into the future.

### Molybdenum-99 Production Facility






The molybdenum-99 Production Facility will be commissioned and commence operations by the end of 2017. It will enable ANSTO to provide up to 25 – 30 per cent of the global demand for molybdenum-99, the precursor to technetium-99m (Tc-99m). Tc-99m is used in 80 per cent of diagnostic nuclear medicine procedures worldwide – approximately 45 million medical procedures every year. The facility will ensure the security of supply of molybdenum-99 for Australia and New Zealand, ANSTO's Molybdenum-99 Production Facility will also go a long way towards mitigating a potential global supply constraint following the shutdown of the major producer in Canada in October 2016, and the shutdown of other suppliers over the coming decade, due to ageing reactors and production facilities. The capability to supply such a large proportion of the world's demand stems from the modern design and scale of the molybdenum-99 Production Facility, the world-leading reliability and productivity of the OPAL reactor, and ANSTO's streamlined production and logistics chains.

This project has particular significance on the world stage as one of the only export-scale molybdenum-99 production processes to exclusively use proliferation-proof low enriched uranium. ANSTO's process positions Australia as a country that exemplifies world's best practice in addressing possible proliferation concerns related to nuclear medicine production, and provides the country with another avenue to advance its non-proliferation principles on the international stage.

ANSTO is delivering a Synroc waste treatment plant, to be co-located with the Molybdenum-99 Production Facility. The plant will deliver a permanent, safe and economical way of managing waste from the past, current and future manufacture of nuclear medicines. Synroc is an exciting Australian innovation that dramatically reduces the volume of waste compared to other methods. ANSTO is aiming for this first-of-a-kind plant to be operational in the fourth quarter of 2019.



# ANSTO'S ROLE IN Driving innovation for health

| STRATEGIC GOAL  | ANSTO LEADERSHIP PROGRESSION | PARTNERSHIPS  | COLLABORATORS   | TECHNOLOGY / PLATFORM   | PRODUCT / SERVICE                      |
|---|------------------------------|---|---|---|--|
| Support the introduction of particle therapy into Australia   | Emergent                     |   | <div>Collaboration of representatives from leading Australian hospitals, research centres, universities and industry</div> <div>  </div> | New particle therapy treatment and research facility (proposed) | Particle therapy methods and protocols |
| Undertake research and provide infrastructure to support the introduction of microbeam radiation therapy in Australia | Emergent                     | <div>  </div> |   | Compact Light Source technology (proposed)                      |  |
| Contribute to the development of next generation accelerators (micro-scanning)  | Emergent                     |   | <div>  </div>  | Next generation accelerators (proposed)                         |  |
| Provide a facility to supply advanced radiotracers for the treatment of disease                                       | Emergent                     |   |   | Iodine-131 facility (proposed)                                  | Iodine-131                             |
| Foster innovation and knowledge transfer between ANSTO, academia and industry to benefit health                       | Emergent                     |   |   | ANSTO Innovation Precinct (proposed)                            |  |

Please note this list does not include all current partners and collaborators.



Credit- Heidelberg Ion-Beam Therapy Center (HIT)



# Key enablers for ANSTO's health strategy

## Project BR—GHT

Through the project BR—GHT, capital expansion project for the Australian Synchrotron, ANSTO has been working closely with universities, research institutes and governments to best respond to the needs of the user community. The addition of new beamlines will allow ANSTO to further bolster academic and industry research outcomes to meet the high demand from local and international researchers for access to synchrotron techniques. Success in this endeavour will complement the secure operational funding stream from NISA, and ensure that Australian research remains at the cutting edge.

Strong early support from stakeholders will enable ANSTO to commence building two new beamlines at the Australian Synchrotron in FY18.



## Nuclear medicine processing and distribution facility

In the coming years, ANSTO will be seeking to undertake a capital program to upgrade its nuclear medicine processing and distribution facility. The current facility at ANSTO has supplied millions of doses of lifesaving medicine to patients and doctors at hospitals and clinics across Australia, but is coming to the end of its operating life. Consequently, a proposal for a nuclear medicine processing and distribution facility that will meet current and future compliance requirements and enables ANSTO to meet increased demand and allows for the introduction of new diagnostic and therapeutic agents for Australia is in development.

The proposed facility will enable ANSTO to continue to provide the reliable processing and distribution of a range of nuclear medicines for current and future Australian health care needs. The facility will be designed to have processing capabilities for products under development or to be introduced into Australia, including lutetium-177, which is currently in clinical trials for the treatment of neuroendocrine tumours. The design will incorporate modern manufacturing techniques, automation and long-term maintainability. The design phase of the plant will leverage domestic and international experience in order to secure the reliable future supply of a range of critical nuclear medicines.



## Partnering for success

Commercial partners are selected based on a strategic fit. This will vary relative to the opportunity. The process takes into account potential partners, current market strength and their future potential. A due diligence process is completed to assess fit, risk and covers areas such as; IP ownership, competition, compatibility with organisational values and implementation ability. There is an internal review process to ensure opportunities match the strategic direction of the organisation.



## Engagement

ANSTO will work with a large group of partners and collaborators at the international, national and regional level to achieve our strategic goals in health.

It will capitalise on existing partnerships and collaborations through the International Atomic Energy Agency (IAEA), nuclear and accelerator organisations and commissions, universities and nuclear regulatory bodies.

ANSTO has a strong presence in the Asia / Pacific region, both in providing access to infrastructure, exchanges of staff, education and training and regional projects.

There are already a number of such projects which will assist to deliver the health strategy, including an investigation into the causes of kidney disease of unknown origin in Sri Lanka and engagement with China on the supply of radiopharmaceuticals.

At the national level, there are strategic partnerships with the Australian National University, Monash University, University of Sydney and University of Western Sydney. We have industry associations with the Australian and New Zealand Society for Nuclear Medicine and a regulator partner in the Australian Radiation Protection and Nuclear Safety Agency. The Australian Institute of Nuclear Science and Engineering links us to the Australian universities.

Participation in the National Imaging Facility (NIF) ensures a contribution to the optimal use of Australian imaging technology through ANSTO's National Research Cyclotron Facility, a joint initiative with the University of Sydney and the Brain and Mind Centre.

More locally, ANSTO has the opportunity to grow an association with a broad health consortium in the greater Sydney region, which includes research organisations, universities and clinical centres.





# Key enablers for ANSTO's health strategy

## Infrastructure

Australia's landmark and national research infrastructure goes to the heart of our ability as a nation to deliver innovation through science and technology developments. Much of Australia's most significant research infrastructure is housed within ANSTO - the OPAL reactor; the National Research Cyclotron Facility; the Australian Synchrotron; the Centre for Accelerator Science; the Australian Centre for Neutron Scattering; the National Deuteration Facility and various imaging facilities enable initiatives and research that benefits human health.

This unique combination of complementary infrastructure within one institution enables ANSTO to meet a key strategic goal in providing solutions to partners, customers, collaborators and users.

The OPAL reactor is essential for the production of radiopharmaceuticals and the production of neutrons for scientific research.

The National Research Cyclotron Facility produces radiopharmaceuticals used in combination with nuclear imaging techniques exclusively for research purposes.

The Australian Synchrotron has a suite of beamlines suitable for biomedical research, including the flagship Imaging and Medical beamline, which provides dynamic X-ray imaging at high resolution. The beamline provides an exciting discovery space for accelerated research into treating tumours, chronic

lung disease, haemorrhage and inflammation of the brain, bone growth and replacement, and various heart-related conditions.

Instruments at the Australian Centre for Neutron Scattering, including Platypus (neutron reflectometer), Quokka (small-angle neutron scattering), and Kookaburra (small-angle neutron scattering) are highly useful for a range of investigation relating to human biology, biological devices and the study of food.

The National Deuteration Facility offers the facilities, staff and expertise to synthesise deuterium labelled molecules for a range of investigations and product developments relevant to causation, detection and treatment of disease, drug delivery, food-lipid digestion and structural biology.

Government's ability to continue to invest in research infrastructure has a direct impact on Australia's ability to participate in supporting local and global health outcomes.



## ANSTO's landmark and national infrastructure supporting Australian health



OPAL multi-purpose reactor



Australian Centre for Neutron Scattering

|            |                                      |
|------------|--------------------------------------|
| Quokka     | Small-Angle Neutron Scattering       |
| Platypus   | Neutron Reflectometer                |
| Kookaburra | Ultra Small-Angle Neutron Scattering |
| Pelican    | Time-of-Flight Spectrometer          |
| Bilby      | Small-Angle Neutron Scattering       |
| Spatz      | Neutron Reflectometer                |



National Research Cyclotron Facility



Australian Synchrotron

|             |  |
|-------------|--|
| IMBL        | Imaging and Medical Beamline             |
| SAXS/WAXS   | Small and Wide Angle X-ray Scattering    |
| MX1 and MX2 | Macromolecular and Micro Crystallography |
| IR          | Infrared Spectroscopy                    |
| XAS         | X-ray Absorption Spectroscopy            |
| XFM         | X-ray Fluorescence                       |



Centre for Accelerator Science

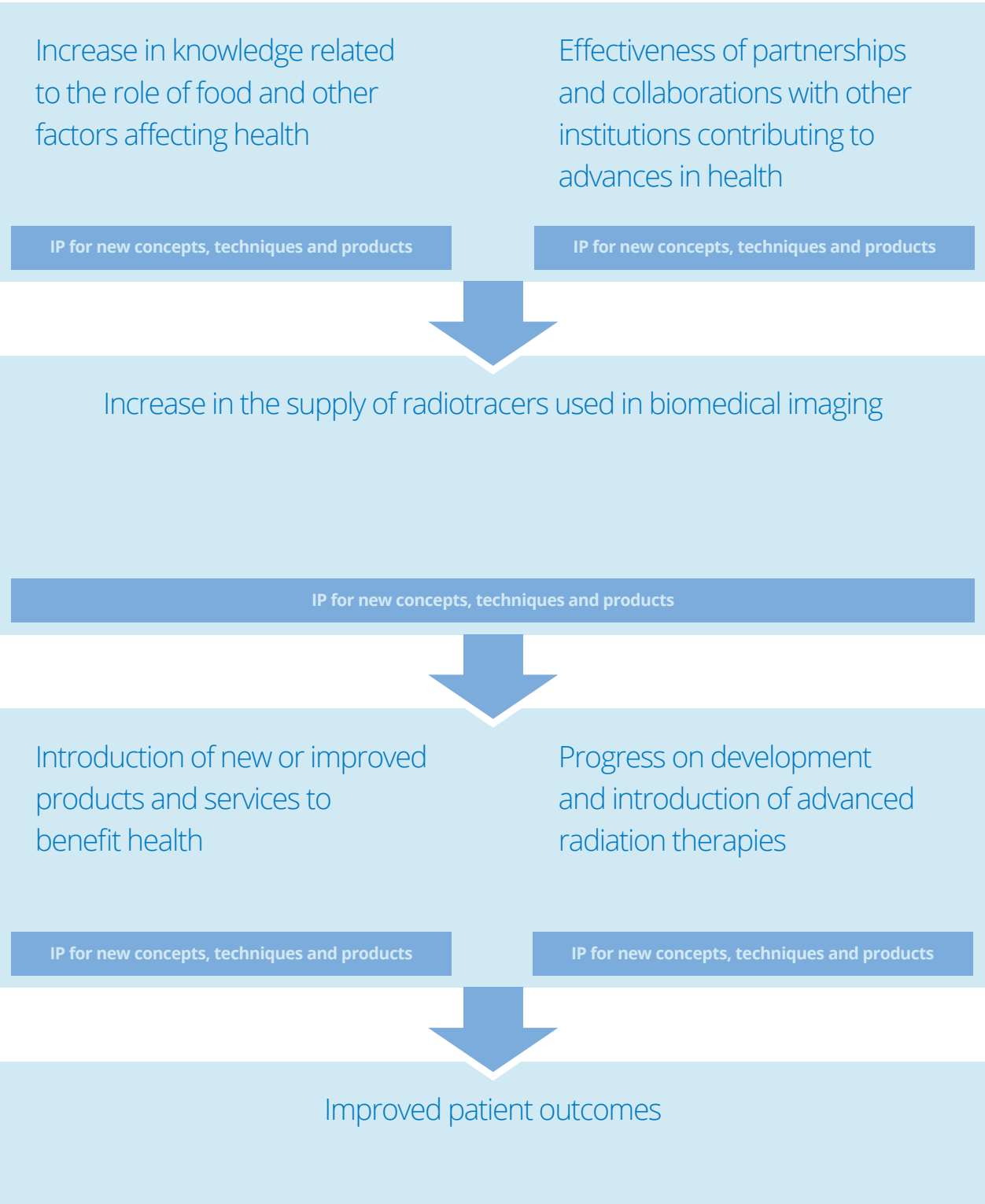


National Deuteration Facility



# How will we determine our success

Our performance with respect to developing tactics to achieve our strategy will be evaluated in the context of:







Australian Government



## Locations

Lucas Heights | Camperdown | Clayton