MTPConnect

Australia's Life Sciences
Innovation Accelerator

FROM MINES TO MEDICINES

AUSTRALIA'S RADIOPHARMACEUTICALS FUTURE

Government of South Australia
Department for Trade and Investment

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MTPCONNECT MINES TO MEDICINES DISCUSSION PAPER

FOREWORD

As Australia's pursuit of excellence in the life sciences sector continues to flourish, the prospect of establishing a globally competitive radiopharmaceutical industry in South Australia presents a unique and unparalleled opportunity. It is why MTPConnect, Australia's Life Sciences Innovation Accelerator, is delighted to spearhead this transformative initiative in collaboration with key stakeholders across the state, Australia and the globe.

South Australia boasts a distinctive advantage that sets it apart on the global stage. The abundance of raw materials derived from its thriving mining industry, world-class tertiary hospitals and research institutions driving health and nuclear innovation, robust clinical trial infrastructure and sophisticated manufacturing facilities enabling advanced production offer an integrated ecosystem that facilitates the entire spectrum of radiopharmaceutical development and utilisation - and an opportunity to drive a unique circular economy.

This comprehensive approach, encompassing the entire value chain from research and development to clinical application and waste management, not only positions South Australia as a leader in the field but also presents opportunities for breakthroughs in cancer treatment and other critical areas of healthcare for better health and wellbeing outcomes.

Furthermore, establishing a radiopharmaceutical industry centred on South Australia but delivering for all of Australia aligns with broader imperatives related to sovereign capability and supply chain security. By fostering domestic expertise and infrastructure in this strategic domain, we enhance our nation's capacity to meet healthcare needs while safeguarding against external dependencies.

As we embark on this journey, I would like to recognise the collaborative efforts of all stakeholders involved; from government entities, hospitals, universities and research organisations to industry partners and investors. Together, we are laying the foundation for a vibrant and sustainable radiopharmaceutical industry that not only benefits South Australia but also contributes to the broader advancement of healthcare in Australia and globally.

Stuart Dignam | **Chief Executive Officer, MTPConnect**

"Australia's radiopharmaceutical industry is at a critical juncture.

If we act now, we can make Australia a global hub for radiopharmaceuticals, building sovereign research, translation and manufacturing capacity to make life saving treatments accessible to Australians."

The Hon. Jaala Pulford | **Chair, MTPConnect**

EXECUTIVE SUMMARY

Right time. Right place. Right now.

South Australia is on the brink of something extraordinary, bridging the gap between two seemingly distant worlds. From the depths of our mines to the delivery of life-saving medicines, South Australia is pioneering a novel, sovereign supply chain for groundbreaking medical treatments. Leveraging vast mineral assets, strategic geographic location, innovation ecosystem and clinical leadership, South Australia is poised to become a leading global player in radiopharmaceuticals. Now is the right time to act and to shape our future in radiopharmaceuticals, **from mines to medicines.**

The vision is to build an end-to-end supply chain in South Australia, creating a world-class hub for manufacturing, research and training in innovative radiopharmaceuticals. This will position the state as a trailblazer and leading manufacturer in Australia and the Asia Pacific, inspiring a new wave of cutting-edge scientific breakthroughs and pioneering treatments. Success would see our region globally recognised for its visionary approach to healthcare and where our commitment to innovation and excellence knows no bounds.

With 165,000 Australians newly diagnosed each year with cancer, a number that's increased more than 80 per cent in 20 years, access to radiopharmaceuticals has the potential to save many thousands of lives.

The global radiopharmaceuticals market is poised for significant growth, with a forecasted value of over $21 billion by 2032 and growing 10 per cent annually[1]. Recent merger and acquisition activity has led to a remarkable 550 per cent increase in venture capital deals in 2023, totalling $626 million in the United States (US) alone. This demonstrates confidence in the sector globally and an appetite for investment[2].

Australia is on the cusp of receiving a new wave of radiopharmaceutical innovations, set to transform patient outcomes and unlock the sector's potential. With this comes an imminent need for local manufacturing and an opportunity to engage in innovative research and clinical development.

But manufacturing radiopharmaceuticals is unlike manufacturing other medicines. They are reliant on radioisotopes extracted from mines and processed into high-value products. They can have shelf lives of just a few hours and need to be manufactured in central locations with rapid transport networks. This is where South Australia's assets are particularly unique—and difficult to replicate elsewhere in Australia or the world.

A thriving radiopharmaceutical industry in South Australia would bring immense benefits to the state and Australia. It promises to significantly elevate health outcomes, offering access to state-of-the-art diagnostic and treatment options while simultaneously reducing healthcare costs through more efficient and effective interventions. It would attract substantial investment from both multinational corporations and domestic entities, bolstered by strategic grant opportunities that accelerate research and commercialisation efforts.

Economically, it would spur growth and diversification, enhancing the region's economic complexity, fostering growth of local companies and opening up avenues for export across Australia and the Asia Pacific. Additionally, it would catalyse the development of a highly skilled workforce, generating specialised jobs aligned with the broader nuclear industry and attracting talent to the region.

The opportunity would foster a unique circular economy, processing South Australia's abundant mining wastes to produce valuable medical products. It would also secure a sovereign supply chain, independent of current geopolitical instabilities in other countries.

This Discussion Paper is a call to action to government and a signal to industry. Through carefully designed strategy, strategic partnership and targeted investment, South Australia's radiopharmaceuticals industry is poised for rapid growth.

To activate the radiopharmaceuticals industry, South Australia's immediate next steps are to:

- Develop a business case
- Convene a cross-departmental advisory committee
- Appoint key personnel to drive strategy
- Establish a radiopharmaceutical innovation accelerator

[1] Precedence Research (2023) Radiopharmaceuticals Market Size, Report By 2032. Retrieved from www.precedenceresearch.com/radiopharmaceuticals-market-size 28 March 2024.

[2] GlobalData (2023) Radiopharmaceutical-focused VC deals in US see staggering 550% growth to $408 million in 2023. Retrieved from www.globaldata.com/radiopharmaceutical-focused-vc-deals-in-us-see-staggering-growth/ 27 March 2024.

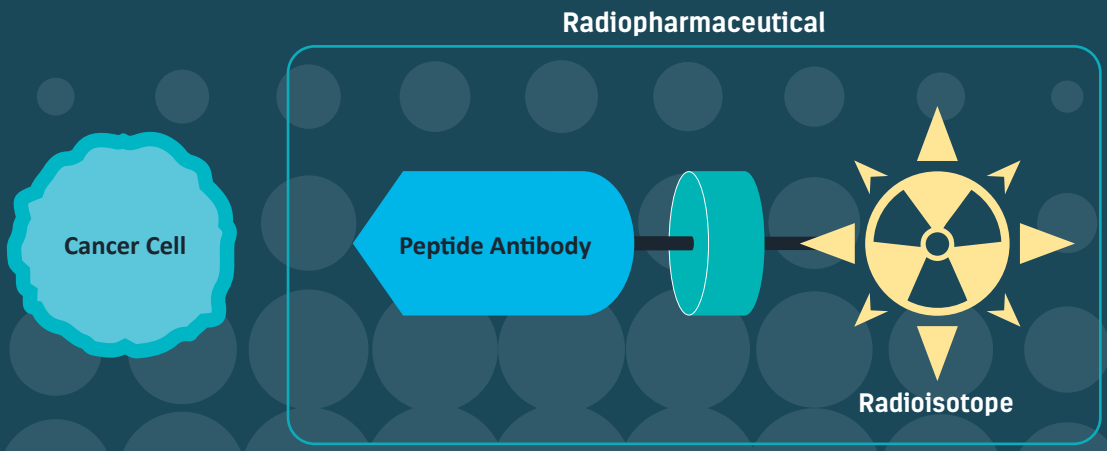
WHAT ARE RADIOPHARMACEUTICALS?

Radiopharmaceuticals are pharmaceutical drugs that contain radioactive forms of chemical elements called radioisotopes (also known as radionuclides). They are used primarily in nuclear medicine for advanced diagnostics such as Positron Emission Tomography (PET) scans, as well as for targeted and precision therapies such as treatments for specific cancers (radioligand therapies). Where radiopharmaceuticals offer both a therapeutic and diagnostic application, they are often referred to as theranostics.

In diagnostic applications, radiopharmaceuticals are primarily used in functional imaging. The radiopharmaceutical is administered orally or intravenously to patients and accumulates in specific tissues or cells. The radioisotope emits radiation which can be detected using advanced imaging techniques such as PET and Single-Photon Emission Computerised Tomography (SPECT). This is used for accurate diagnosis and staging of a range of conditions including cancer, heart disease, neurodegenerative diseases, lung disease, gastroenterological disorders and more recently in acute inflammatory conditions and serious infective disorders. Imaging technology has advanced significantly in the last five years with increased resolution, sensitivity and hybrid technology such as PET-MRI paving the way for improved diagnoses as well as expanding research opportunities.

In therapeutic applications, radiopharmaceuticals or radioligand therapies are used to treat various medical conditions such as certain forms of cancer or hyperthyroidism. Targeted therapy for thyroid cancer has a history of over 80 years. More recent radiopharmaceuticals have been developed to treat metastatic neuroendocrine tumours (NET), prostate cancer and various other malignancies.

These radiopharmaceuticals often contain a targeting molecule (such as a monoclonal antibody, protein, peptide or small molecule) which binds to specific cancer cells or molecules in the body where the radiation is then delivered. The aim is to destroy or control the growth of diseased cells while minimising damage to surrounding healthy tissue. This approach is commonly known as precision medicine, in contrast to traditional systemic chemotherapy which may impact healthy cells as well.



SOURCING RAW RADIOISOTOPE MATERIALS

Many of the elements used to produce radioisotopes are sourced from natural deposits in the earth's crust. For example, uranium and thorium which are used as target materials in nuclear reactors for radioisotope production are typically mined from uranium ore deposits. Raw materials for radioisotope production in Australia are sourced locally and from around the globe. Of note is a significant reliance on Ytterbium, only available commercially from Russia, to produce Lutetium-177 used extensively in imaging and therapy. Other sources of radioisotopes and raw materials come from the US, Japan and Europe. Australia's reliance on overseas-sourced materials presents a challenge for sufficient and stable supply, subject to geopolitical influences.

Advanced processes and technologies, developed in South Australia, offer new avenues for sourcing raw radioisotope materials and securing Australia's supply chain. They recover and process valuable isotopes from low-level radioactive mining waste streams and convert them into valuable pre-cursor materials for radiopharmaceuticals. This is further described in 'A Circular Economy' on page 23.

PRODUCTION OF RADIOPHARMACEUTICALS

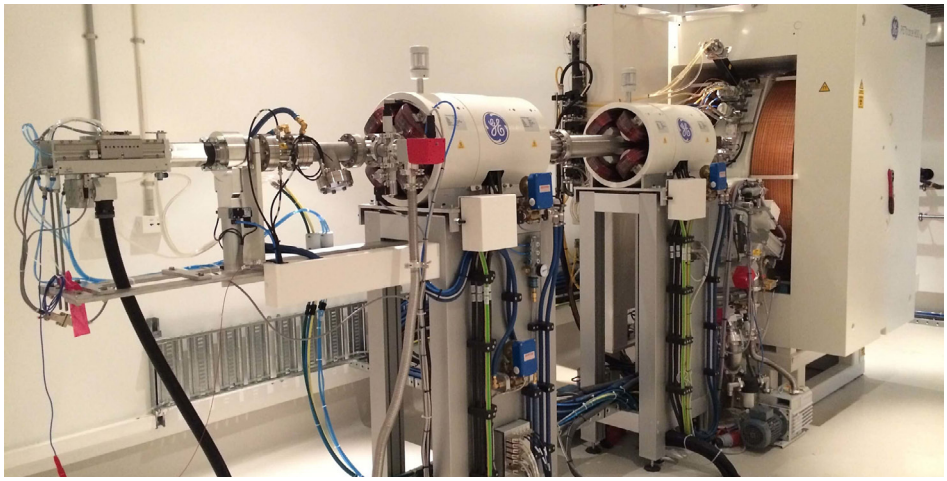
Radioisotopes used in radiopharmaceuticals are commonly manufactured within specialised facilities employing nuclear reactors or particle accelerators such as cyclotrons.

High-energy accelerators (HEAs) function at exceptionally high energy levels, typically within the giga-electron volt (GeV) to tera-electron volt (TeV) range and are not currently available in Australia.

Small medical cyclotrons (SMCs) are compact particle accelerators tailored for localised production of specific radioisotopes, offering flexibility and on-site generation benefits. They are used commonly to produce radiopharmaceuticals used in PET imaging. In contrast, medium-energy cyclotrons (MEC) are larger and capable of producing a wider range of radioisotopes for various applications in diverse scientific and industrial fields including isotope generation for medical imaging, nuclear physics research and material analysis. Additionally, advancements in technology have spurred the development of isotope generators including benchtop models currently under development within Australia.

A target material is irradiated with high-energy particles (such as neutrons or protons) to induce nuclear reactions that result in the formation of the desired radioisotope. For targeted radiopharmaceuticals, this radioisotope is “radiolabelled” - chemically bound to a targeting molecule to form the radiopharmaceutical.

This process is highly specialised and regulated to ensure safety and effectiveness. In Australia, facilities gain approval from the Therapeutic Goods Administration (TGA) for each of the therapeutic products produced and must comply with standards such as Good Manufacturing Practices (GMP), Good Laboratory Practice (GLP) and current Good Radiopharmacy Practice (cGRPP). This is in addition to compliance with general work, health and safety (WHS) as well as Chemical and Radiation safety regulations.



Molecular Imaging and Therapy Research Unit SAHMRI - 2021

IMPACTS OF HALF-LIFE

All radioisotopes are unstable and undergo radioactive decay. This is how they produce radiation and a fundamental characteristic of their utility. Half-life refers to the time it takes for half of the radioactive atoms to undergo radioactive decay and is an indicator of the expiration time of a radiopharmaceutical. Different medical use isotopes have different decay properties with half-lives from minutes to hours which influence their suitability for specific applications.

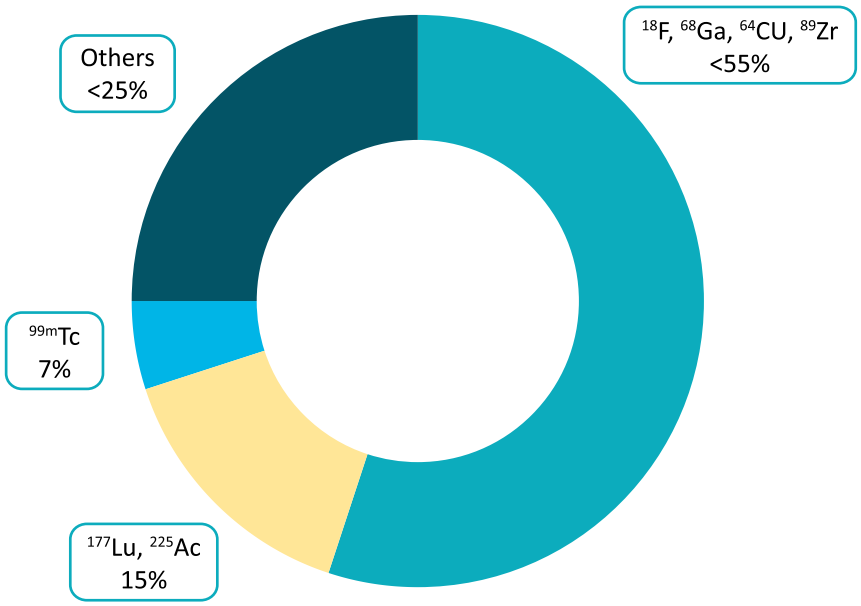
For diagnostic imaging, radiopharmaceuticals with shorter half-lives are preferred because they allow for faster clearance from the body, reducing radiation exposure to patients and improving image quality. For therapeutic applications, radiopharmaceuticals with longer half-lives are often desired to ensure a sufficient radioisotope uptake by the diseased tissue to have optimum therapeutic effect.

The half-life of a radioisotope presents significant challenges in the manufacture and distribution of radiopharmaceuticals. Manufacturers must carefully coordinate production schedules to align with clinical demand while minimising radioactive decay during transportation and distribution. Additionally, the short half-life limits the geographical distribution range of radiopharmaceuticals as they must be delivered to medical facilities within a limited timeframe to maintain sufficient radioactivity for imaging or therapy.

COMMON TYPES OF RADIOISOTOPES

Common diagnostic radiopharmaceuticals currently in use include technetium-99m, iodine-123 and fluorine-18. Among these, technetium-99m stands out as the most commercially successful radioisotope. Its labelled products having been used for imaging since the 1960s with tens of millions of medical diagnostic procedures now performed annually across the globe. The second most widely used radiopharmaceutical is Fluorodeoxyglucose (FDG) which is used for imaging cancer cells with a PET scanner. In the therapeutic domain, iodine-131, lutetium-177, lead-212, actinium-225 and radium-223 are among the commonly used radiopharmaceuticals.

However, the use of radioisotopes in radiopharmaceuticals is shifting with the introduction of innovative diagnostics, therapeutics and theranostics. Approximately 55 per cent of radiopharmaceuticals under development are labelled with fluorine-18, gallium-69, copper-64 or zirconium-89, primarily serving diagnostic functions. Approximately 15 per cent of those under development are drugs labelled with lutetium-177 and actinium-225[3].



Use of radioisotopes in radiopharmaceuticals Research by Radionuclides

[3] Medraysintell (2024) Nuclear Medicine Report & Directory, 10th Anniversary edition [PowerPoint slides]. Retrieved from https://www.medraysintell.com/_files/ugd/1beeab_82397f0fb509445592773540df476e2e.pdf 2 April 2024

CASE STUDY: LUTETIUM-177

Lutetium-177 is the most in-demand radioisotope for preclinical research, as well as human studies. The landmark FDA approvals in 2018 for Lutetium-177 DOTA-TATE to combat NETs, followed by the 2022 approval of Lutetium-177 vipivotide tetraxetan for advanced metastatic prostate cancer, have spurred significant investments from both public and private sectors, driving further exploration and development of Lutetium-177's potential across diverse clinical applications.

In 2020, the most diagnosed cancer in South Australian males was prostate cancer, accounting for 30.7 per cent of all male cancers. Prostate cancer is currently the most well researched area in radiopharmaceuticals and the most commercially successful, with positive trial publications in highly respected clinical journals using Lutetium-177–PSMA ligands for Prostate-Specific Membrane Antigen (PSMA)-positive metastatic castration resistant prostate cancer. Since 2018, the Molecular Imaging and Therapy Research Unit (MITRU) of the South Australian Health and Medical Research Institute (SAHMRI) has been pivotal in the local manufacturing of Lutetium-177-PSMA ligands in South Australia, facilitating crucial clinical trials and compassionate use initiatives.

In addition to these FDA approved products Novartis have a pipeline of new radiopharmaceuticals and line extension trials planned. However, they are not the only international pharmaceutical company interested in Lutetium-177. Last year, Eli Lilly acquired Point Biopharma Global for USD$1.4 Billion. Point Biopharma has three lead trials of innovative radiopharmaceuticals, all using Lutetium-177 as the therapeutic radioisotope.

In Australia, Lutetium-177 is imported from Europe and currently, only manufactured locally at Australian Nuclear Science and Technology Organisation (ANSTO). An observation about the long-term opportunities of Lutetium-177 has been noted by Australian private companies, such as entX (SA) and Silex Systems (NSW), who are investigating technologies for extracting valuable starter materials from mining and medical waste. Establishing domestic production of Lutetium would further enhance Australia's position in the global radiopharmaceutical landscape.

WHERE ARE WE NOW? GLOBALLY

Systemic radiopharmaceutical medicines as therapies for cancer were first introduced in the 1940s when physicians used radioactive iodine for the treatment of thyroid cancer. However, due to their lack of potency and associated side effects stemming from their lack of specificity, researchers and clinicians have strived to enhance safety and efficacy by conjugating radioisotopes with targeting molecules like tumour-specific small molecules, peptides or antibodies.

This pursuit has led to the emergence of second-generation radiopharmaceuticals in oncology sparking renewed interest in the field and driving substantial dealmaking and increased venture financing. By 2022, approximately 120 radiopharmaceuticals were marketed worldwide, though many were only accessible in limited regions, contingent upon approvals and manufacturing capacity. Among them, therapeutic radiopharmaceuticals constituted 20 per cent of the global market, a figure expected to soar to 70 per cent by 2032[4].

Radiopharmaceuticals Market — Therapies — Diagnostics

The sector's growth is due to:

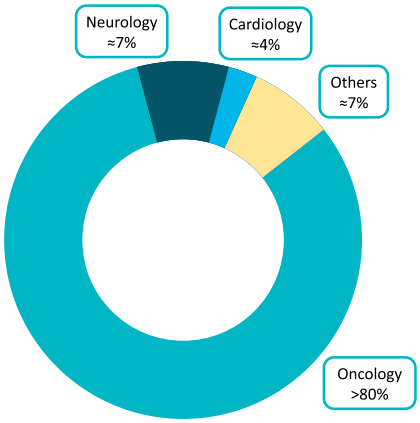
1. **Increasing incidence of cancer** with associated demand for radiopharmaceuticals in diagnosis and treatment. New cancer cases worldwide are expected to exceed 20 million each year by 2025.
2. **Advances in imaging technologies** such as PET and SPECT, leading to greater use of radiopharmaceuticals for diagnosis and disease monitoring.
3. **Aging population** with higher susceptibility to relevant chronic diseases, such as cancer and neurodegenerative disorders which radiopharmaceuticals can diagnose and treat.
4. **Technological innovations** through ongoing research discovery and development.
5. **Growing awareness and demand** among healthcare practitioners and patients resulting in increased adoption of personalised medicine and radiopharmaceutical use.
6. **Government investment** in healthcare infrastructure including nuclear medicine facilities.
7. **Expanded application** of radiopharmaceutical use beyond oncology to areas such as neurology and cardiology.

[4] Medraysintell (2024) Nuclear Medicine Report & Directory, 10th Anniversary edition [PowerPoint slides]. Retrieved from https://www.medraysintell.com/_files/ugd/1beeab_82397f0fb509445592773540df476e2e.pdf 2 April 2024

WHERE ARE WE NOW? GLOBALLY

With hundreds more radiopharmaceuticals currently in development, primarily focusing on oncology[3], the global radiopharmaceuticals market is on a steady upward trajectory, projected to reach $21 billion by 2032[1]. Despite currently being smaller than traditional therapeutic modalities, the sector's robust compound annual growth rate (CAGR) of around 10 per cent and promising long-term prospects have attracted considerable investment interest. This is evidenced by merger and acquisition activity of over US$17.1 billion in the last eight years and a remarkable 550 per cent growth in venture capital deals to $626 million in 2023, up from $97 million in 2017[2].

+$21B
By 2032
10% CAGR



Research by diseases - Potential of nuclear medicine to address unmet medical needs.

This investment surge has garnered the interest of 20 global pharmaceutical companies, either actively engaging in nuclear medicine or establishing dedicated research and development initiatives within the field, including major players such as Novartis, Bayer, Eli Lilly, GE Healthcare, AstraZeneca, Merck and Lantheus.

Novartis is the global leader. Their radiopharmaceutical portfolio includes an extensive pipeline of products used for cancer treatment spanning twelve products across fifteen indications. Their radioligand therapy (RLT) for the treatment of PSMA-positive metastatic castration resistant prostate cancer spearheads the portfolio and is approved by the United States Food and Drug Administration (FDA) for this indication.

The pharmaceutical sector is experiencing a notable shift with increasing recognition of the potential of nuclear medicine to address unmet medical needs. This trend is expected to attract more investment from pharmaceutical companies and institutional investors, leading to accelerated clinical development and paving the way for enhanced diagnostic and therapeutic solutions.

For pharmaceutical companies to commercialise and deliver emerging radiopharmaceutical therapies, they will need to establish manufacturing and supply chains within local geographies, due to both technical and economic factors.

KEY INDUSTRY DRIVERS

When speaking with industry about their business activities in Australia, a consistent theme is apparent regarding the need for a commercial return environment for manufacturers of original pharmaceutical and medical device products. In order to bring research to market, and commit to the necessary investments in infrastructure, manufacturing and R&D activities, companies require a viable commercial pathway for patient access to therapies. This includes sophisticated regulatory and reimbursement environments that facilitate broad and equitable patient access to new therapies

Australia has long been recognised as a favourable environment to undertake clinical trials. It has also been recognised as a challenging but potentially profitable environment for introducing new pharmaceutical products. Policy and regulatory settings can have a significant impact on the decisions of local and international companies to invest in Australian research and development.

The regulatory and reimbursement pathways for radiopharmaceuticals are unclear and lengthy, given their simultaneous use in diagnosis and treatment. Navigating and creating a commercialisation pathway from both a regulatory and reimbursement perspective is a key challenge for radiopharmaceutical companies, looking for confidence in a path to market to decide to commercialise.

KEY INDUSTRY DRIVERS

Several factors influence the industry's decisions to commercialise and invest in radiopharmaceuticals in Australia (including South Australia):

1. **Clear and efficient market access pathway** to enable rapid commercialisation and translation into clinical practice, providing confidence for international companies to invest in the Australian radiopharmaceutical ecosystem. This requires streamlined regulatory and reimbursement approvals.

    - **Regulatory approval** for product use, manufacture, handling and transportation. The regulatory environment for radiopharmaceuticals is complex. In addition to approvals from the TGA for product use, radiopharmaceuticals are subject to tight regulation due to potential radiation exposure throughout their lifecycle. Oversight comes from various agencies such as the Australian Radioactive Waste Agency (ARWA), ANSTO and the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). Additionally, state-specific licensing approval is required for the transport or handling of radioactive material, overseen by entities like South Australia's Environmental Protection Agency (EPA). While this is discussed in more detail relating to logistics in this paper, it is worthwhile noting the challenges of navigating multiple regulatory processes to the point of a patient receiving treatment. Strict protocols are followed to ensure patient safety and specialised training is required for healthcare professionals involved in handling and administering these agents. There are some differences between Australia's regulatory system for new products and the international standards which need to be navigated, potentially causing delays in Australians accessing innovative treatments.

    - Equitable patient access through reimbursement of the costs of therapies and diagnostics. The current Australian medical reimbursement codes are not suitable for new and emerging therapies and diagnostic products. For such products to be listed on the Pharmaceutical Benefits Scheme (PBS) or receive a specialised code through the Medicare Benefits Scheme (MBS), a decision-making process involving the Pharmaceutical Benefits Advisory Committee (PBAC) or the Medical Services Advisory Committee (MSAC) may be required. Unfortunately, hospitals have no financial incentive to label and dispense innovative products if they cannot claim rebates from the available codes. Therefore, further research is needed to explore this issue. Additionally, there is a possibility of implementing novel reimbursement approaches such as a combination of state and federal reimbursement models for TGA registered, GMP certified radiopharmaceuticals as seen in the case of cell and gene therapies in Australia.

KEY INDUSTRY DRIVERS

2. **Reliable source of isotopes** for both clinical trials and commercial scale activities. The end-to-end process of sourcing materials, manufacturing, transporting and delivering radiopharmaceuticals relies on a robust ecosystem of capabilities, infrastructure, workforce and logistics. The decaying radioactive properties and disparate logistics regulatory requirements add complexity to achieving this need. South Australia's supply chain, infrastructure and regulatory environment surrounding logistics are discussed in detail further in this paper. Support is required to enable innovative radiopharmaceutical companies in Australia to manufacture locally.

3. **Specialised workforce** across the entire supply chain from research, development, manufacture, transport and clinical service delivery. This requires Nuclear Medicine Specialists, Radiochemists, Nuclear Medicine Technologists and Medical Physicists. Further to this, industry also seeks leading clinicians and researchers to lead clinical trials and champion translation into practice. An opportunity exists to attract investment to build workforce capability with the potential to align with South Australia's broader nuclear workforce capability development priority.

4. **Research and clinical trials infrastructure** to develop and bring new radiopharmaceuticals to market. These facilities provide essential infrastructure, patient populations and expertise to identify emerging technologies, develop solutions and conduct robust trials, expediting development programs, manufacturing scale-up, regulatory approval and successful commercialisation.

5. **Clinical infrastructure** including hospitals, imaging facilities and clinicians to deliver clinical services to patients.

Overall, key industry drivers reinforce the need for strategic policy and regulation innovation to bring industry, academia and government together to align potential with activity and to capitalise on South Australia's advantages and develop a thriving radiopharmaceuticals industry.

Creating a path to market for the next wave of radiopharmaceuticals has the potential to unlock the radiopharmaceutical industry opportunity.

THE AUSTRALIAN CONTEXT

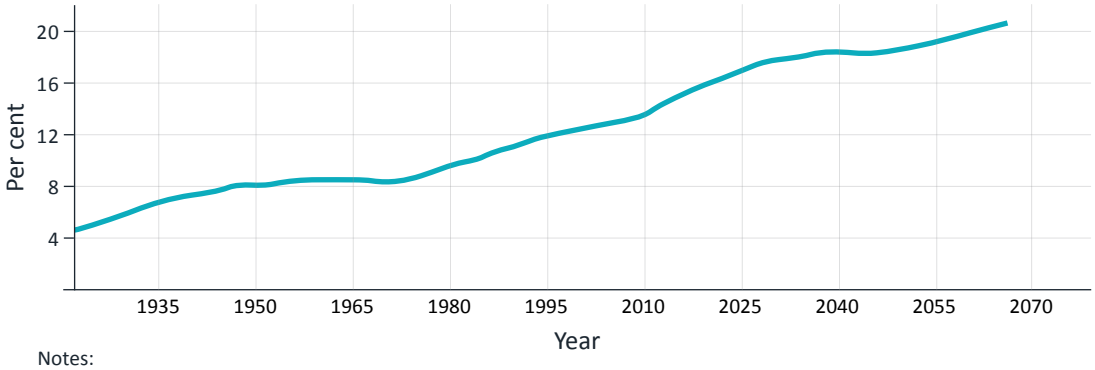
Radiopharmaceuticals arguably represent the most significant breakthrough the world has seen in the management of cancer in the 21st century.

With more than 1.1 million Australians impacted by cancer at some point in their lives and 165,000 Australians newly diagnosed each year, access to radiopharmaceuticals has the potential to save many thousands of lives.

Of concern, around 12 per cent of all cases with one of the five most commonly diagnosed cancers present with advanced or Stage IV cancer.

By 2033, it is estimated more than 200,000 cases of cancer will be newly diagnosed in Australia each year and by 2040, with Australia's ageing and increasing population, that number will climb to nearly 2 million people.

Percentage of the Australian Population aged 65 and over, at 30 June, over time



Notes:
1. Data for 1921 to 1970 are population estimates. Data from 1971 onwards are estimates of the resident population (ERP).
2. Population data from 1992 to 2011 are recast estimates following the rebasing of the 2011 Census. For more information, see the ABS expienatory notes

Sources: ABS 2018, 2019. www.aihw.gov.au

The nation's very best medical research institutions cannot meet current demand for radiopharmaceuticals, with many thousands of patients desperate to be treated. Current efforts to secure regulatory approval for the first innovative therapeutic radiopharmaceutical are poised to unlock the industry's potential and facilitate future theranostic applications in the country. This progress is expected to attract investment and stimulate commercialisation, driving growth in the sector.

Innovative radiopharmaceutical development companies in Australia such as Telix, Clarity Pharmaceuticals, GlyTherix, Radiopharm Theranostics and AdvanCell represent a burgeoning opportunity. While Telix stands out as the only company currently with a product on the market, others like Clarity Pharmaceuticals are close behind, with lead products advancing through Phase III trials and a recently announced $121 million investment round. These companies have fostered partnerships with South Australian entities, leveraging resources and expertise to drive progress, such as through technology licenses, collaboration agreements and clinical trials activity.

THE AUSTRALIAN CONTEXT

Despite their innovative products and partnerships, many of these companies face challenges in Australia's current regulatory and reimbursement pathways, prompting investment in manufacturing facilities closer to accessible markets overseas. For example, Telix Pharmaceuticals, who are a global company headquartered in Melbourne, has invested in manufacturing facilities and cyclotrons in Belgium and the United States.

Opening up the local market would unlock opportunities for domestic manufacturing of radioisotopes and radiopharmaceuticals. Currently, in Australia, radioisotopes for radiopharmaceuticals are produced in thirteen cyclotrons located around the country, and the Open-pool Australian Lightwater (OPAL) nuclear reactor located in ANSTO in New South Wales. While SAHMRI's cyclotron is a notable South Australian asset, ANSTO's OPAL reactor is crucial for radioisotopes like lutetium-177, technetium-99m and gallium-68. This reliance highlights the importance of collaboration and coordination across facilities to ensure consistent access to a wide range of radioisotopes for both commercial and research applications. It also demonstrates the value of capitalising on novel technologies, such as waste processing and novel generators.

Australian companies such as AdvanCell, Cyclopharm, entX and Silex are at the forefront of developing innovative technologies or processes for isotope production, complementing traditional methods and expanding the range of radioisotopes available for manufacturing. AdvanCell and Cyclopharm are developing generator technologies, entX has developed proprietary processing technology and Silex's lasers isotope separation technology represents a cutting-edge approach for uranium enrichment.

The emergence of new radiopharmaceuticals that address unmet needs will also lead to a rising demand for local research and clinical trials. However, this will be reliant on agile radiopharmaceutical manufacturing facilities. In South Australia, opportunities for research and clinical trial activity are currently being lost due to a lack of capacity in both manufacturing infrastructure and workforce.

Australia's radiopharmaceuticals workforce is underdeveloped, primarily due to the insufficient availability of professionals with specialised expertise. This shortage of skilled personnel poses a significant obstacle to the growth and advancement of the sector in meeting demand, driving innovation and effectively leveraging new technologies. Addressing this skills gap at the national level is imperative to ensure the long-term viability and success of Australia's radiopharmaceutical industry.

While there are limited efforts to bridge the gap, there's an opportunity for a national approach to coordinating credentialled workforce development. Notably, in 2023 two ARC Industry Transformation Training Centres (ITTC) received funding. Monash University secured $5 million for the ARC Training Centre for Radiochemical Technologies and Precision Radiopharmaceuticals, aimed at training the next generation of radiochemists and advancing molecular techniques for utilising radioactivity, with partners including ANSTO, GlyTherix Ltd, Cyclotek (Aust) Pty Ltd, Telix Pharmaceuticals Limited, Adalta Limited and Neurosolutions Ltd. Additionally, the Australian National University (ANU), in collaboration with the University of South Australia (UniSA) and University of Adelaide, received $5 million to establish the ARC Training Centre in Radiation Innovation, enhancing the nation's capabilities in sectors reliant on nuclear and radiation science and policy.

Australia's Strengths

- Unique mineral assets
- Globally renowned research and education institutions
- Attractive research and development incentives
- Trusted regulatory environment
- Innovative isotope production methods
- Pipeline of innovative nuclear and medical research
- Australian radiopharmaceutical companies reaching global markets

Australia's Challenges

- Limited patient access to advanced treatments
- Slow reimbursement pathways
- Reliance on overseas mining resources
- Limited scalability of existing manufacturing facilities
- Poor research translation
- Workforce shortages
- Complex transport and handling regulations across the nation
- Unreliable logistics

CASE STUDY:
TELIX PHARMACEUTICALS & APOMAB

Telix Pharmaceuticals is a publicly listed Australian company focused on developing radiopharmaceuticals for prostate, kidney, brain (glioblastoma), and haematologic cancers, as well as rare diseases. Their lead product is an imaging radiopharmaceutical set for imminent sales in the US, Canada and Australia for the detection of prostate cancer.

Telix has acquired manufacturing capabilities in Belgium and the United States to ensure a reliable global supply chain, manufacturing and distribution network. Although they do not currently have a corporate presence in South Australia, since 2019 they have been working with AusHealth to develop APOMAB, a targeted radiation therapeutic for ovarian and lung cancer, discovered at the Royal Adelaide Hospital (RAH).

A SOUTH AUSTRALIAN RADIOPHARMACEUTICALS INDUSTRY

THE UNIQUE SOUTH AUSTRALIAN OPPORTUNITY

South Australia stands as the singular state with all the essential elements to sustain a radiopharmaceuticals industry for Australia.
The state's unique position as a comprehensive hub, spanning from mining operations to advanced pharmaceutical manufacturing, underscores its unrivalled capability to lead the way in revolutionising healthcare through radiopharmaceutical innovation.

The establishment of a radiopharmaceuticals industry in South Australia not only promises significant economic development through job creation, investment attraction and export opportunities but also brings tangible benefits to patients through improved access to cutting-edge treatments and therapies. Furthermore, by fostering the growth of a skilled workforce and driving innovation in the healthcare sector, this initiative contributes to the overall enhancement of the state's workforce capabilities and reinforces its position as a leader in medical research and innovation.

Benefits to South Australia would include:

1. **Improved health outcomes**
   - Access to cutting-edge diagnostic and treatment options
   - Reduced overall healthcare costs by minimising unnecessary interventions and enhancing treatment outcomes
2. **Investment attraction**
   - Investment from multinational and Australian companies
   - Strategic grant opportunities to accelerate research and commercialisation
3. **Economic growth**
   - Increased economic complexity
   - Local company growth
   - Opportunities for export within Australia and the Asia Pacific region
4. **Skilled workforce and jobs creation**
   - Specialised skills development
   - Talent attraction
   - Jobs creation aligned with broader nuclear industry development
5. **Unique circular economy**
   - Capitalising on and processing unique assets in SA mines and waste tailings
   - Recovering valuable isotopes for the production of precursors for medical diagnostics and treatment
6. **Sovereign supply chain**
   - Breaking the reliance on existing supply chains in countries with increasing instability arising from geopolitical issues

A CIRCULAR ECONOMY

In South Australia, a unique opportunity arises within the field of radiopharmaceuticals as manufacturing processes capitalise on waste generated from mining operations. Waste from mining for energy production has the potential to be processed into a valuable starting material for radiopharmaceuticals. This innovative circular economy strategy aligns with national and state-level initiatives aimed at maximising resource utilisation and minimising waste disposal.

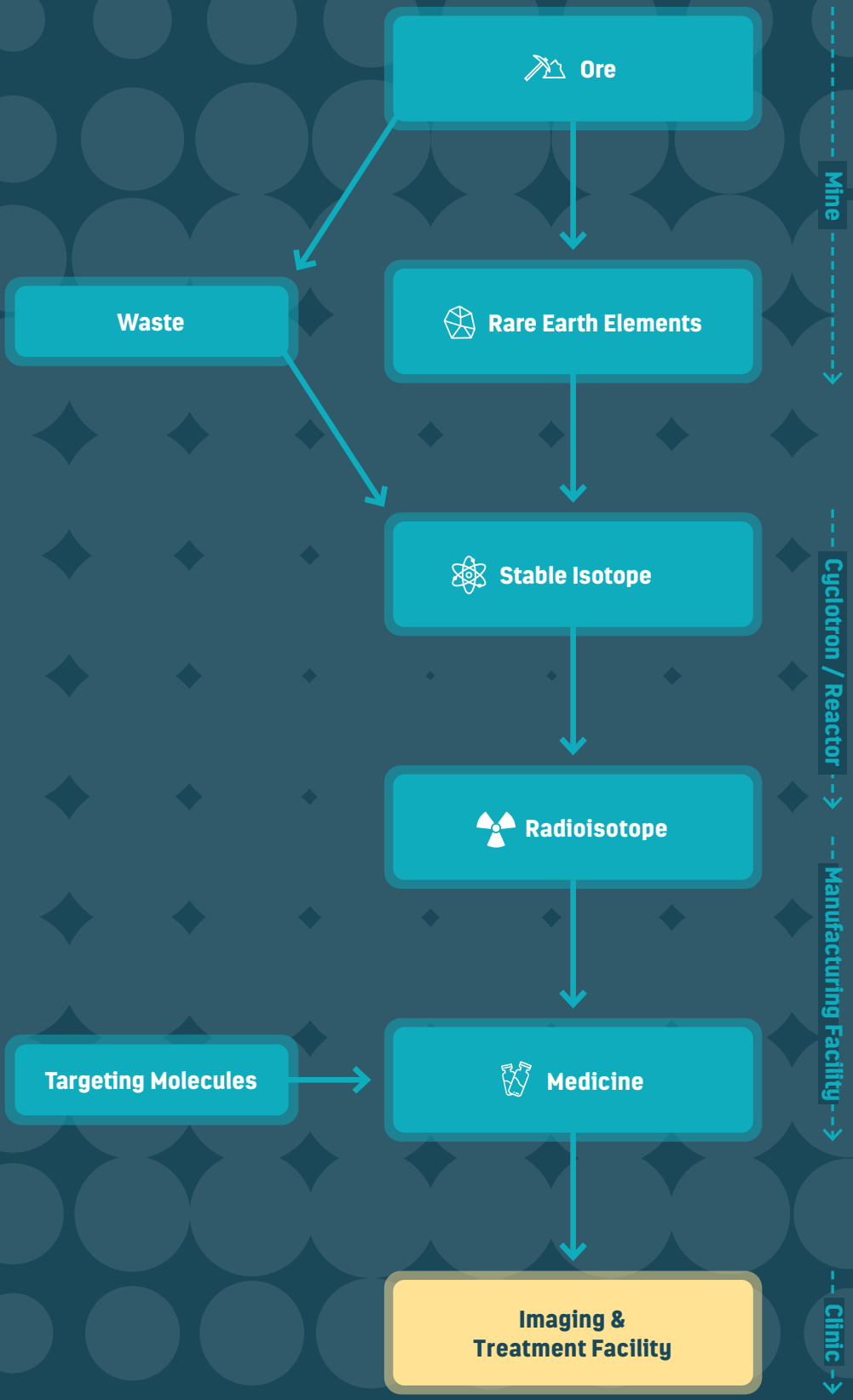
Federally, the Department of Climate Change, Energy, the Environment and Water has outlined ambitious waste diversion targets, including a goal to divert 80 per cent of all waste from landfill by 2030. Similarly, South Australia's Resource Recovery Strategy and Action Plan 2020-2028, supported by the City of Adelaide Council, envisions Adelaide as the first city in Australia to achieve 'zero avoidable waste to landfill.' Notably, private companies have also seized the opportunity to engage in waste recycling, particularly the recycling of mining tailings for use as starter materials in the production of radiopharmaceuticals.

This symbiotic relationship between mining waste utilisation and radiopharmaceutical manufacturing not only underscores South Australia's unique position to drive innovation and sustainability but also presents a significant advantage in fostering a circular economy within the nuclear medicine sector.

SECURING OUR SUPPLY CHAIN

The South Australian Advanced Manufacturing Strategy highlights the current fragility of supply chains in the state and the importance of securing local capability and resources. The radiopharmaceutical sector and associated healthcare delivery is a prime example, due to a heavy reliance on imported key elements such as Ytterbium, often sourced from Russia. Ytterbium-176 is found in monazite ores in Olympic Dam and currently left as unprocessed waste.

Supply shortages from events such as the pandemic and geopolitical tensions have demonstrated the vulnerability of the radiopharmaceutical supply chain. Furthermore, reliance on foreign producers can lead to monopolies, higher prices and unreliable service while dependence on a limited number of suppliers risks eroding sovereign production capabilities. From a security perspective, Australia's lack of influence over global isotope distribution poses risks and geopolitical factors can impede progress in health research and treatment advances.



Radiopharmaceuticals Industry Supply Chain

LEVERAGING OUR ASSETS

South Australia has end-to-end capability and significant competitive advantages as a location to build a thriving radiopharmaceuticals industry.

- **Abundant uranium resources:** South Australia possesses significant uranium deposits which serve as a crucial raw material used in the production of common radioisotopes such as Lutetium-177. In fact, Olympic Dam contains the world's largest uranium resource and South Australia is home to 25 per cent of the world's decaying uranium deposits.

- **Untapped thorium and radium deposits:** Thorium and radium are emerging as valuable precursors for radiopharmaceutical production. For example, Radium-226 can be used as a precursor for Actinium-225 which is increasingly being used in new treatments. It is currently being stockpiled in the US by companies seeking to manufacture large quantities of innovative therapies. Radium-226 can be found in South Australia's mineral waste streams alongside appropriate processing capability.

- **Capabilities and the ideal environment for recycling mining waste:** Locally mined uranium is processed and exported overseas with redundant mineral left unprocessed at sites as waste. South Australian company entX has proprietary technology to use mining waste to produce radioisotopes for medical use. This innovative approach offers environmental benefits and further ensures a sustainable source of radioisotopes. Furthermore, the location of mining sites are ideal for high-risk processing. Other Australian sites with technological capacity such as ANSTO could not undertake this manufacturing process due to the risk of escaping radioactive gases.

- **Strategic geographic location:** Adelaide's location and central airport provides access to domestic and international markets, facilitating the timely distribution and export of radiopharmaceutical products. The state's well-developed transportation infrastructure including ground and air enables efficient logistics and connectivity with key markets across Australia and within the Asia Pacific. Further to this, an inherent advantage within the state is the flexibility to provide suitable manufacturing and processing sites for handling of dangerous goods.

- **Uniquely skilled workforce:** Boasting expertise in nuclear physics, radiation science and related disciplines, South Australia is a leader in training medical physicists and nuclear medicine technologists working across Australia and the globe. The presence of specialised programs and research initiatives, such as the ITTC for Radiation Innovation, underscores this specialised workforce. Furthermore, with the ongoing nuclear shipbuilding projects in the defence sector, South Australia continues to cultivate a skilled and specialised workforce with knowledge in nuclear technologies and safety protocols.

LEVERAGING OUR ASSETS

- **Established manufacturing and clinical facilities:** With local production of clinical-grade radiopharmaceuticals, locally owned imaging facilities, experienced oncologists and dedicated oncology clinical trials facilities, South Australia offers a robust infrastructure for radiopharmaceutical development, manufacturing and clinical implementation.

- **Track record in radiopharmaceutical innovation:** Across South Australia, institutions like the RAH and Queen Elizabeth Hospital (QEH) exemplify a longstanding commitment to radiopharmaceutical research, development and clinical practice. With over 50 years of experience, these institutions have established themselves as leaders. Their expertise extends to the development of novel radiopharmaceuticals for various medical purposes including inflammation imaging and theranostics applications. The RAH continues to be a leading site globally for studies in pancreatic cancer.

- **Convergent research and innovation ecosystem:** South Australia is home to world-class research institutions, universities and medical centres that specialise in nuclear medicine. However, it is South Australia's convergence of diverse fields such as drug discovery and development, nuclear technology and mining that has the potential to drive global advancements in radiopharmaceuticals. For example, the synergy between nuclear medicine and drug discovery enables the development of novel, targeted theranostics. Additionally, South Australia's strong presence in the nuclear and mining sectors provides access to essential resources and infrastructure for radioisotope production while fostering innovation in extraction techniques and waste management.

- **Strong regulatory framework:** Australia upholds high standards of regulatory oversight and safety in the healthcare, pharmaceutical and nuclear sectors, providing assurance to global investors, manufacturers and consumers regarding the quality, reliability and safety of domestic radiopharmaceutical production. Furthermore, Australia's Clinical Trial Notification (CTN) scheme offers rapid approval for clinical trial activity in comparison with other nations.

- **Attractive incentives for attracting global companies:** Australia's generous R&D Tax Incentive supports companies to undertake research and clinical trials in Australia. It offers eligible entities a tax offset for qualifying activities, effectively reducing the cost of innovation and encouraging investment in cutting-edge research and development initiatives like radiopharmaceuticals.

By leveraging these strengths, South Australia has the potential to establish itself as a leading hub for radiopharmaceutical innovation, manufacturing and commercialisation, contributing to advancements in healthcare and driving economic growth.

CASE STUDY: ARC TRAINING CENTRE IN RADIATION INNOVATION

The Australian National University (ANU) in partnership with the University of South Australia (UniSA) and University of Adelaide has been awarded $5 million from the Australian Research Council (ARC) to bolster the nation's capabilities in sectors underpinned by nuclear and radiation science and policy.

The ARC grant, together with matching investment by the three universities and 16 partners across industry and government, has been used to establish the ANU-led Australian Research Council (ARC) ITTC in Radiation Innovation (RadInnovate). The Training Centre will create a leading-edge workforce with sophisticated skills in nuclear and radiation science, policy and regulation.

RadInnovate students will receive hands-on training from Australia's experts in nuclear science and engineering, governance and regulations, ethics, science communication and inclusion across three universities and through being embedded in industry and government placements and attending industry-specific courses.

RadInnovate will deliver nationally networked, sovereign training that is driven by industry needs and will include programs to increase diversity in science as well as socially and environmentally responsible innovation.

The partners on the Training Centre are:

- Advanced Robotics for Manufacturing Hub
- AdvanCell Isotopes
- Australian Bragg Centre for Proton Therapy and Research
- ANSTO
- ARPANSA
- ARWA
- CSIRO
- Babcock
- Defence SA
- Defence Science and Technology Group
- entX Limited
- Quantum Brilliance
- Queensland Health
- Reforme Minerals
- Skykraft
- BHP Olympic Dam Corporation

SOUTH AUSTRALIA'S LEADERS

ENTX
Mineral Extraction & Processing

EntX, a publicly listed Adelaide-based company, is revolutionising radioisotope production by using advanced processes to convert mining waste into valuable precursor materials. They collaborate with local universities and global companies and plan to generate commercial quantities of medical isotope precursors in 2024. EntX is also establishing international processing plants and licensing proprietary engineering processes globally.

SMARTWAYS
Logistics

SmartWays is an Australian medical logistics company with headquarters in Sydney and a hub in Adelaide. They specialise in delivering complex logistics in healthcare and have expertise in transport of radiopharmaceuticals across different jurisdictions in Australia and New Zealand.

ADVANCELL ISOTOPES
Radiopharmaceutical Production

New South Wales company, AdvanCell, maintains a research and development facility within The Braggs Building of The University of Adelaide. They are developing a pipeline of radiopharmaceuticals, as well as a novel desktop generator for production of alpha radioisotopes, ideal for targeted therapies.

THINK & ACT DIFFERENTLY, POWERED BY BHP
Mineral Extraction & Processing

Think & Act Differently, Powered by BHP are focused on delivering the resources of tomorrow by empowering people to Think & Act Differently today. They collaborate with people from within and outside the mining industry to co-create bold and forward-thinking aspirations to deliver resources the world needs in new ways.

MITRU - MOLECULAR IMAGING AND THERAPY RESEARCH UNIT, SOUTH AUSTRALIAN HEALTH & MEDICAL RESEARCH INSTITUTE
Radiopharmaceutical Production

MITRU houses South Australia's only cyclotron for the research, development, and manufacture of radiopharmaceuticals. MITRU supplies TGA approved radiopharmaceuticals daily to hospitals and imaging centres across Australia, including FDG, PSMA, and Lu-177 therapeutics under the Special Access Scheme. Recent equipment acquisitions have extended MITRU's capability to produce fluorine, copper, zirconium, and lutetium radioisotopes.

SOUTH AUSTRALIA'S LEADERS

JONES RADIOLOGY
Imaging & Treatment

Jones Radiology is a private radiology practice with clinics across South Australia and the Northern Territory. They offer imaging and therapeutic services, including nuclear medicine. Their partnership with SAHMRI led to the establishment of the Clinical Research and Imaging Centre (CRIC), which provides advanced imaging facilities, including the first Photon Counting Computer Tomography (PCCT) scanner in Australia.

BENSON RADIOLOGY
Imaging & Treatment

One of the largest radiology practices in the nation, Benson Radiology is another privately owned, South Australian company. Of their 25 clinics, five offer nuclear medicine.

RADIOLOGY SA
Imaging & Treatment

Radiology SA is a privately owned, Adelaide-based radiology practice, run by radiologists and nuclear medicine specialists for the medical community.

SA MEDICAL IMAGING
Imaging & Treatment

South Australia Medical Imaging (SAMI) is a state-wide government owned medical imaging service, including Nuclear Medicine services that provides specialist, multi-disciplinary services to patients in 10 public hospitals across South Australia. It is the largest public imaging provider in Australia. With over 1200 staff, they conduct around 690,000 examinations per year and are active in teaching and research.

QSCAN
Imaging & Treatment

Qscan Radiology Clinics is a comprehensive diagnostic medical imaging and interventional practice with clinics across Australia. They have one clinic in South Australia, providing PET scanning and therapy.

CENTRAL ADELAIDE LOCAL HEALTH NETWORK (CALHN)
Imaging & Treatment

CALHN hosts two Nuclear Medicine departments, at RAH and QEH, which are operated by SAMI and service different patient groups. Collectively, they are experienced in novel radiopharmaceutical product development and clinical trial services, have led global radiopharmaceutical discoveries and are actively involved in over 50 clinical trials using radiopharmaceuticals.

Established more than 50 years ago, the RAH's Department of Nuclear Medicine is one of the leading Tertiary Nuclear Medicine services in Australia. It houses South Australia's two publicly owned PET scanners. The Department has a long-standing history of radiopharmaceutical manufacturing, suppling products to South Australia and across Australia. Today, in the absence of a TGA approved facility, the experienced team manufactures and supplies for local use.

CASE STUDY: QUEEN ELIZABETH HOSPITAL AND NEUROENDOCRINE TUMOURS

South Australia has a track record in the treatment of NETs using radiopharmaceuticals, showcasing notable success in an area where treatment options are typically limited. NETs, encompassing a diverse spectrum of tumours primarily affecting the gastrointestinal tract, lungs, bronchi, thymus and pancreas present a formidable challenge due to their rarity and complexity.

The QEH, supported by funding from the SA Area Health Service, Hospital Research Foundation Group and Neuroendocrine Cancer Australia (formerly the Unicorn Foundation), has been at the forefront of treating NETs with 177Lutetium-octreotate since 2011. This groundbreaking approach gained further validation in 2022 with the introduction of the OCLURANDOM trial in France, marking a pivotal moment in NETs research and treatment. The trial's findings underscore the potential of 177Lutetium-octreotate to revolutionise the management of this cancer subtype, offering a promising alternative to conventional treatment modalities. This convergence of innovative research and effective clinical practice in South Australia not only highlights the region's leadership in medical advancements but also signifies a significant leap forward in improving patient outcomes and reshaping treatment paradigms for NETs globally.

SOUTH AUSTRALIA'S LEADERS

PRE-CLINICAL IMAGING AND RESEARCH LABORATORY (PIRL), SOUTH AUSTRALIAN HEALTH AND MEDICAL RESEARCH INSTITUTE (SAHMRI)

Research, Development & Training

SAHMRI also operates a specialised research facility, Pre-clinical Imaging and Research Laboratory (PIRL), located on 35-acres at Gilles Plains. The facility is ideal for radiopharmaceutical pre-clinical studies due its unique combination of accredited small and large animal research capability alongside advanced imaging expertise, including PET/CT and SPECT scanners.

AUSHEALTH CORPORATE

Research, Development & Training

AusHealth Corporate, a commercial entity owned by the Central Adelaide Local Health Network, generate profits from services and products delivered on behalf of the healthcare system. They reinvest these in a portfolio of health innovations, including a new radiopharmaceutical to treat lung and ovarian cancer, APOMAB. AusHealth have partnered with Melbourne-headquartered Telix Pharmaceuticals to fund their first-in-human trial.

NEW ADELAIDE UNIVERSITY

Research, Development & Training

The new, merged Adelaide University will build critical mass in radiopharmaceuticals, building on the notable capabilities from both the University of South Australia (UniSA) and The University of Adelaide. Collectively, they have expertise spanning research, education, and industry collaboration in nuclear medicine, radiation science, pharmaceutical sciences, drug discovery and cancer research. Researchers are collaborating with industry partners, such as BHP, AdvanCell and entX to undertake cutting edge research in areas such as radiotracer development, radiochemistry, molecular imaging, and novel targeted radiopharmaceuticals.

MOLECULAR IMAGING AND THERAPY RESEARCH UNIT, SOUTH AUSTRALIAN HEALTH & MEDICAL RESEARCH INSTITUTE

Research, Development & Training

In addition to manufacturing, MITRU has a track record in research and development of novel radiopharmaceuticals. They have long standing relationships with large Australian radiopharmaceutical organisations like Clarity Pharmaceuticals and Telix Pharmaceuticals, and have recently signed a collaboration agreement with Australian company, GlyTherix, to provide manufacturing scaleup expertise to support an early-stage trial of a novel radiopharmaceutical for prostate, pancreatic and bladder cancers.

Last year, MITRU, in collaboration with AdvanCell, University of South Australia and the University of Adelaide, were awarded funding through the Medical Research Future Fund (MRFF) National Critical Research Infrastructure (NCRI) grant opportunity. The initiative will create the Australian Research Network for Translation of Targeted Alpha Therapies (TAT) and enable MITRU to acquire new infrastructure to extend its GMP manufacturing capabilities and produce targeted alpha therapies.

MITRU provides graduates the opportunity to work across many areas and as such is an ideal real world training environment for chemists, physicists, engineers, material scientists and quality assurance personnel.

SOUTH AUSTRALIA'S LEADERS

CANCER RESEARCH SOUTH AUSTRALIA (CRSA)

Clinical Trials

CRSA is a private organisation of local medical oncologists in South Australia. They established a facility in Adelaide, near St Andrew's Hospital, and commenced their first clinical trial using radiopharmaceuticals last year in partnership with the hospital.

CMAX

Clinical Trials

CMAX is Australia's longest established, independent facility for early phase clinical trials and is headquartered in Adelaide BioMed City. Since 1993, CMAX has collaborated with clinical units, imaging and pharmaceutical companies. They are experiencing increasing demand from radiopharmaceutical companies and exploring activity in this space.

FLINDERS UNIVERSITY

Research, Development & Training

Last year, Flinders University entered into significant partnerships with global universities to partner in nuclear undergraduate and postgraduate qualifications. Responding to the need to build a skilled South Australian workforce to support the impending Australia, United Kingdom, United States (AUKUS) submarine construction, the new educational programs cover a range of relevant topics to bolster Australia's nuclear capabilities.

CURRENT LIMITATIONS

Although South Australia's radiopharmaceuticals sector has significant potential for growth, it currently faces several issues and challenges in addition to the Australian challenges mentioned above.

- **Lack of sector coordination and governance:** The absence of coordinated efforts and governance structures hinders the efficient allocation and utilisation of resources within the radiopharmaceuticals sector. Furthermore, it limits the potential knowledge exchange and collaborations between participants within the sector.

- **Limited manufacturing capacity:** There is only one medical cyclotron in South Australia, located at SAHMRI. Although it can meet current demand, it requires additional infrastructure and personnel for scalability, quality and reliability. The facility has untapped physical capacity, with the potential for existing clean rooms to be fitted with further manufacturing equipment.

- **Limited diagnostic imaging equipment:** South Australia's public health system is equipped with only two PET scanners, a stark contrast to other states. Both scanners are situated at the RAH, resulting in limited patient accessibility and reliance on private facilities. Additionally, the absence of cutting-edge diagnostics like Total-Body and digital PET scanners further exacerbates the situation. This deficiency not only affects clinical services but also hinders advanced imaging research and diminishes the region's appeal to researchers.

- **Undefined market access pathway:** The absence of a clear pathway for market access for novel radiopharmaceutical products in Australia creates uncertainty for pharmaceutical companies and manufacturers, impedes local research and clinical development activity and ultimately delays Australian patients access to potentially life-saving treatments.

- **Poor incentives for optimising mining waste management:** Attempts to extract waste materials, including non-radioactive rare earths, from mine tailings have faced challenges due to commercial viability and safety concerns, limiting opportunities for collaboration with major mining companies. The Albanese Government's announcement of a $2 billion expansion of the Critical Minerals Facility aligns with the broader Critical Minerals Strategy 2023-2030, aiming to transform the processing of critical minerals within Australia. Leveraging this policy and creating incentives for mining companies to process waste for uses, such as radiopharmaceuticals, will be of significant benefit to the environment, the medical science sector and the health of Australians.

ACTIVATING A SOUTH AUSTRALIAN RADIOPHARMACEUTICAL INDUSTRY

What the industry will need to grow and flourish in South Australia

	Challenges	Solutions
Coordinated strategy and sector leadership Shared vision and leadership driving cohesive industry development and a unified local supply chain	Fragmented sectors and organisations pursuing disparate goals	Establish a specialised team to oversee the strategy and implementation, and empower engagement by sector stakeholders
Secure supply chain A robust supply of the required minerals and chemicals to produce specific radioisotopes	Reliance on overseas mining resources	Transform the local supply chain through innovative waste processing
Scalable manufacturing capabilities Facilities with the requisite equipment, expertise and processes for timely and quality production and distribution to clinics	Limited scalability of existing manufacturing facilities	Coordinate and expand research and manufacturing facilities, ensuring close alignment with clinical treatment sites
Rapid market access Accessible and equitable clinical capability and equipment to diagnose and treat patients	Limited patient access to advanced treatments and slow reimbursement pathways for TGA registered, GMP certified products	Ensure timely market access to TGA registered, GMP certified products within States, complemented by clear pathways for national reimbursement
Attractive research and innovation pipeline Local innovation assets being developed for global markets and attracting international investment	Poor research translation	Accelerate research translation through strategic investment
Skilled workforce Talented people with the skills and experience to meet the industry's high and diverse demands	Workforce shortages	Identify and address workforce gaps through training, incentives and talent attraction strategies

ACTIVATING A SOUTH AUSTRALIAN RADIOPHARMACEUTICAL INDUSTRY

	Challenges	Solutions
Seamless logistics Location and efficient logistics solutions for timely product delivery within Australia and the APAC region	Complex transport and handling regulations across the nation and unreliable logistics	Harmonise and simplify regulatory and logistics processes
Industry attraction South Australia as a location for strategic investment by multinational companies seeking research and development, clinical trials, manufacturing and distribution	Limited engagement by multinational companies in local ecosystem	Expand intermediary and promotional activities, targeted at attracting multinationals to South Australia
Positive community sentiment Australians supporting local radiopharmaceutical developments and proud to be employed within the industry	Lack of awareness and misconceptions about radiopharmaceuticals and 'nuclear' medicine	Implement a targeted communications, education and engagement strategy to the broad community

IMMEDIATE NEXT STEPS

Action now will help position South Australia as a vital hub for radiopharmaceuticals. This can be achieved through collaboration between industry and government, a coordinated strategy and then building public and private sector capability. This paper recommends the following initial actions:

Develop a business case Develop a Statewide Strategy and Business Case for the activation of a Radiopharmaceuticals Industry for consideration by the Premier and Ministers. The Strategy and Business Case will outline South Australia's vision and contribution to the expanding global sector, detailing actionable steps and anticipated returns to position the state for significant social and economic benefits. The Strategy would be led by MTPConnect with support from the Department of Premier and Cabinet.	May 2024 – June 2025 (interim report by December 2024)
Convene a cross-departmental advisory committee South Australian Government to establish an Inter-Departmental Committee led by the Department of Premier and Cabinet to work with industry, consumers, academics and government to advise Government on the Radiopharmaceuticals Industry Strategy implementation.	July 2024 - ongoing
Appoint key personnel to drive strategy • Appoint a Radiopharmaceuticals Sector Champion within MTPConnect, a new dedicated role committed to advocacy, strategy leadership, implementation and global business development.	May 2024 - ongoing
• Appoint a health economist to analyse market dynamics, evaluate policy interventions, provide evidence on cost-effectiveness of innovative radiopharmaceuticals and inform decision-making.	July 2024
Establish a radiopharmaceutical innovation accelerator Establish a South Australian radiopharmaceutical innovation fund, a public-private partnership, for research, capability building, industry investment, and facilitating access to the latest TGA registered GMP certified products.	Launch January 2025

RECOMMENDED ACTIONS

This paper also provides a suite of recommended actions that should be considered by stakeholder groups, industry and governments. The following recommendations are required actions to build a thriving Radiopharmaceuticals industry in Australia. Some recommendations can be actioned quickly, while others may require further examination.

- * indicates “Next Steps” recommendations

COORDINATED STRATEGY AND SECTOR LEADERSHIP

Australia

- Australian Government to establish the Australian Radiopharmaceuticals Industry Advisory Body to report to the relevant Minister/s and provide advice on policy and regulation required across Australian Government departments and bodies to support the Radiopharmaceutical industry

South Australia

- Establish a consumer and stakeholder group to inform strategy and implementation
- South Australian Government to establish an Inter-Departmental Committee led by the Department of Premier and Cabinet to work with industry, consumers, academics and government to advise Government on the Radiopharmaceuticals Industry Strategy implementation*
- Appoint a Radiopharmaceuticals Sector Champion within MTPConnect, a new dedicated role committed to advocacy, strategy leadership, implementation and global business development*
- Appoint a dedicated health economist for the radiopharmaceutical sector to analyse market dynamics, evaluate policy interventions, provide evidence on cost-effectiveness of innovative radiopharmaceuticals and inform timely decision-making*
- Attract a global Key Opinion Leader in theranostics within the Department of Health and Wellbeing to attract innovative clinical trial activity and champion clinical practice

RECOMMENDED ACTIONS

SECURE SUPPLY CHAIN

Australia

- Undertake an analysis of Australia's supply chain, sovereign capability and global reliance for the range of current and future radioisotopes

South Australia

- Establish and operate a dedicated mining waste processing facility which provides access for research and commercial manufacturing purposes
- Invest in waste processing research and innovation that addresses current gaps in Australia's sovereign supply chain now and strengthens future export opportunity

SCALABLE MANUFACTURING AND IMAGING CAPABILITIES

Australia

- Explore infrastructure options that provide priority access for radiopharmaceutical research, commercial production and clinical service delivery

South Australia

- Undertake an analysis of current capacity and future requirements for manufacturing and clinical delivery of radiopharmaceuticals in South Australia
- Develop a coordinated strategy, that considers both public and private resources, for scaling manufacturing and clinical activity
- Expand the capacity of MITRU at SAHMRI to enable scalable production and distribution across Australia and the Asia Pacific
- Invest in further imaging infrastructure, such as additional PET scanners and advanced technologies

RAPID MARKET ACCESS

Australia

- Review current regulatory and reimbursement processes for innovative radiopharmaceuticals and establish an efficient framework to hasten patient access to TGA registered, GMP certified products and build industry confidence in delivering therapies to Australians
- Establish appropriate MBS reimbursement codes for radiopharmaceuticals

South Australia

- Provide funding for early patient access to innovative TGA registered, GMP certified radiopharmaceuticals for South Australians prior to approval of reimbursement codes, in the interests of attracting multinationals to invest in infrastructure, manufacturing, research and development within the State

RECOMMENDED ACTIONS

ATTRACTIVE RESEARCH AND INNOVATION PIPELINE

Australia

- Include radiopharmaceuticals as a stand-alone Medical Research Future Fund (MRFF) Priority
- Identify radiopharmaceuticals as an area of interest under the National Reconstruction Fund's Medical Science Priority Area
- Establish targeted funding schemes, such as the MRFF and the ARC Emerging Researchers Award (AEA) to support radiopharmaceuticals research and innovation, including research into mining waste processing that generates valuable isotope precursors in the radiopharmaceutical supply chain

South Australia

- Establish a South Australian radiopharmaceutical innovation fund, a public-private partnership for research and translation, capability building, industry investment, and market access to the latest TGA registered GMP certified products*
- Appoint dedicated research positions in radiopharmaceuticals within our research organisations
- Lead a Cooperative Research Centre (CRC) proposal in radiopharmaceuticals innovation

SKILLED WORKFORCE

Australia

- Conduct an analysis of Australia's future workforce needs relative to the current workforce and identify existing pathways for workforce development across Australia
- Invest in efforts to address skills shortages, establish specialised training programs, provide ongoing professional development opportunities and raise awareness about career pathways in radiopharmaceuticals
- Establish incentives to encourage career development within the sector e.g. scholarships, internships
- Develop a global talent attraction strategy, including adding radiopharmaceutical roles to the skilled visa list

South Australia

- Develop and offer a Radiation Chemistry degree at the new Adelaide University
- Establish local incentives in partnership between government and industry, for career development within the sector e.g. Industry Doctoral Training Centre (IDTC)
- Upskill the local research and clinical workforce, leveraging existing programs and capabilities such as MITRU's graduate cyclotron training
- Embed nuclear medicine into the significant work being undertaken in South Australia to develop a nuclear workforce to support AUKUS commitments

RECOMMENDED ACTIONS

SEAMLESS LOGISTICS

Australia

- Review regulatory requirements for the handling and transportation of radiopharmaceuticals across Australia and within states and create a framework that achieves harmonisation, efficiency and reliability (particularly as it relates to commercial airline transportation)

South Australia

- Review the Environment Protection Authority (EPA)'s regulatory handling and transportation of radiopharmaceuticals and optimise for efficiency and reliability

INDUSTRY ATTRACTION

South Australia

- Appoint a dedicated intermediary to develop a pro-active stakeholder engagement program, facilitate partnerships and attract industry and investment to South Australia
- Develop a unique value proposition and messaging for attracting talent, companies, collaborations and investment to South Australia

POSITIVE COMMUNITY SENTIMENT

Australia

- Design and implement a targeted communications, education and engagement strategy with the broader community

GLOSSARY OF ACRONYMS

ANSTO	Australian Nuclear Science and Technology Organisation
ARC	Australian Research Council
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ARWA	Australian Radioactive Waste Agency
AUKUS	Australia, United Kingdom, United States Security Agreement, a trilateral security partnership
cGRPP	Current Good Radiopharmacy Practice
CRIC	Clinical Research and Imaging Centre
CRSA	Cancer Research South Australia
CSIRO	Commonwealth Scientific and Industrial Research Organisation
FDG	Fluorodeoxyglucose, a radiopharmaceutical used in positron emission tomography (PET) scans
GLP	Good Laboratory Practice, a system ensuring the quality and integrity of non-clinical laboratory studies
GeV	Giga-electron Volt
GMP	Good Manufacturing Practice, a system ensuring the quality and consistency of pharmaceutical production
HEA	High Energy Accelerator
ITTC	Industrial Transformation Training Centre
MBS	Medicare Benefits Schedule, a list of medical services subsidised by the Australian government's Medicare program
MEC	Medium Energy Cyclotron
MITRU	Molecular Imaging and Therapy Research Unit
MRFF	Medical Research Future Fund
MSAC	Medical Services Advisory Committee, an Australian government committee that evaluates new medical services for public funding.
NCRI	National Critical Infrastructure initiative
NET	Neuroendocrine Tumour
Nuclear Medicine	A medical specialty that uses radioactive substances for imaging and treatment of various diseases
PBAC	Pharmaceutical Benefits Advisory Committee, an Australian government committee that advises on the listing of medications on the PBS
PBS	Pharmaceutical Benefits Scheme, a program in Australia that subsidises the cost of prescription medications.
PCCT	Photon Counting Computed Tomography
PET	Positron Emission Tomography, a medical imaging technique
PSMA	Prostate-Specific Membrane Antigen
QEH	Queen Elizabeth Hospital
Radioisotope	An isotope of an element that exhibits radioactivity, often used in medical imaging or treatment
Radiopharmaceutical	A pharmaceutical drug that contains a radioactive substance, used in nuclear medicine for diagnostic or therapeutic purposes

GLOSSARY OF ACRONYMS

Radionuclide	A radioactive form of an element that may be used in medical imaging or treatment
RAH	Royal Adelaide Hospital
RLT	Radioligand Therapy, a form of targeted therapy that uses radiopharmaceuticals to deliver radiation directly to cancer cells
SA	South Australia
SAHMRI	South Australian Health and Medical Research Institute
SAMI	South Australia Medical Imaging
SMC	Small Medical Cyclotron
SPECT	Single-Photon Emission Computed Tomography, a nuclear medicine imaging technique
TAT	Targeted Alpha Therapies, a type of cancer treatment using alpha-emitting radionuclides
TeV	Tera-electron Volt
TGA	Therapeutic Goods Administration, the regulatory body for therapeutic goods (medicines, medical devices, etc.) in Australia
Theranostics	The integration of diagnostic and therapeutic procedures, often using the same agent for both
UniSA	University of South Australia
US	United States
WHS	Work, Health and Safety

APPENDIX

CONSULTATION PROCESS

The consultation process for this discussion paper included:

- extensive desktop research, encompassing thorough examination of literature, reports, and online resources
- review of key documents and information supplied by listed contributors
- structured interviews with all listed contributors, representing:
    - diverse stakeholder groups spanning research, government, industry and clinical interests
    - local, national and global perspectives
- independent review and consolidation of pertinent information
- regular stakeholder engagement, including alignment with state and federal government agencies
- document review by key contributors
- online workshop with core contributors to refine concepts and elicit feedback

An independent consultant, with more than 20 years of global expertise in the radiopharmaceuticals industry, was enlisted to compile an information dossier and conduct initial interviews, while additional consultancies were solicited to assist in the formulation of key messages.

Throughout the endeavour, the team at MTPConnect undertook the primary responsibility for preparation of this Discussion Paper and associated Prospectus.

MTPConnect

Australia's Life Sciences
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