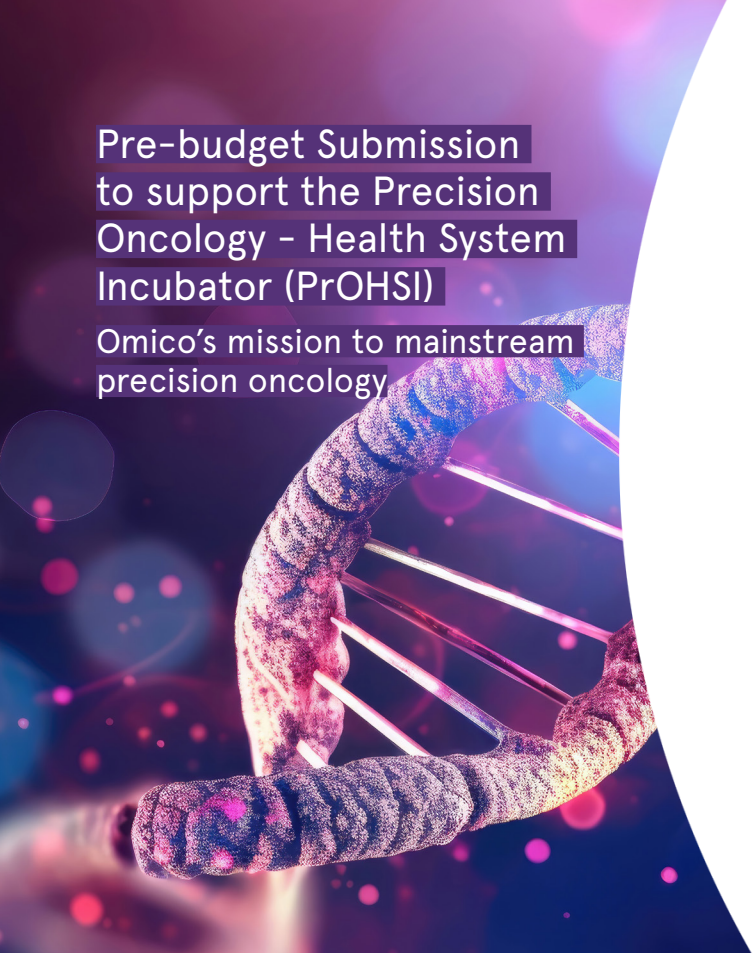
Pre-budget Submission to support the Precision Oncology - Health System Incubator (PrOHSI)

Omico's mission to mainstream precision oncology



Overview

Omico is positioned to drive the next step change for patients with rare cancers through the Precision Oncology Health System Incubator (PrO-HSI) program. Building on the success of our Precision Oncology Screening Platform enabling Clinical Trials (PrOSPeCT) initiative, which has provided genomic tumour profiling for over 17,000 patients, PrO-HSI will expand access to advanced therapies and address key recommendations from the Health Technology Assessment (HTA) Review Report and Senate Inquiry. With a capped government investment model, PrO-HSI offers value for money to deliver a fundamental improvement in access to treatments for Australians who most need it and can be implemented within existing policy and legislative frameworks. However, without additional funding, the vital infrastructure developed over the past eight years could be lost, hindering our mission to accelerate precision oncology and leaving many patients without access to the advances of science.

As a generic model, a Health System Incubator introduces a pioneering approach to overcome the challenges of transitioning groundbreaking healthcare solutions into routine clinical care. It creates new pathways for the sustainable integration of health innovations while addressing systemic barriers to access and implementation, particularly for underserved populations and unmet healthcare needs. The concept leverages combined investment from the public and private sectors to foster collaboration between healthcare stakeholders and unify health ecosystems. The model could serve as a blueprint for other health priorities beyond cancer and is scalable to address other diseases with a high societal burden.

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Omico's vision for PrO-HSI

- Enable free genomic tumour profiling for 5000 eligible* rare cancers patients per year, and direct patients to effective targeted therapies.
- Implement a pay-for-performance model to provide immediate access to tumour-agnostic treatments for ~750 patients per year, with government reimbursement limited to the 40% of patients expected to respond to treatment. †
- Match ~1760 patients per year to clinical trials, boosting R & D investment in Australia and providing access to advanced therapies funded by industry.
- Collect real world data and develop a health economic model with evidence that reduces uncertainty and demonstrates the value of precision oncology for patients with high unmet needs.

** Patient eligibility determined by a pre-specified list of rare cancers which recognises both anatomically (tumour location) and histologically (tissue) based criteria developed in collaboration with the Australian Institute of Health and Welfare. † Industry to fund the cost of treatment for non-responders.*

PrO-HSI derisks government investment in healthcare innovation. Capped at $30 million AUD per year, PrO-HSI contains costs, with data-driven options for timely implementation, modification, or withdrawal, alongside a program-level evaluation for cost-effectiveness. If the program meets the value threshold, the data collected during PrO-HSI could be used to support an application for broad reimbursement for all rare cancer patients through PBAC and MSAC processes.

It is difficult to overstate the significance of this for Australian rare cancer patients, who account for one in five cancer deaths.

Enabling PrO-HSI relies on critical infrastructure built by Omico over the past 8 years, supported by federal and state health departments, the Department of Industry, Science and Resources (DISR), and industry. The final installment of DISR funding is expected in June 2025, with the final patient to be enrolled in our existing programs by the end of 2025. Beyond this, there is a risk of losing essential infrastructure.

Developed in consultation with key stakeholders including patient advocacy groups, clinicians, and industry, the concept continues to receive strong support. We anticipate it will take 12 to 24 months to develop a detailed, investable program model with a potential launch in early 2027 (if not sooner). To bridge this funding gap, Omico will require new funding starting in 2026.

Omico is uniquely positioned to deliver PrO-HSI

Omico's successes highlight the critical social value of investing in science and innovation to improve health outcomes for Australians, while also supporting a strong life sciences sector that benefits the economy. Its role as an "honest broker" enables Omico to engage with industry while representing the national interest, making it a valuable partner for the Government.

Existing infrastructure developed with > 300 M AUD in public and private funding:

- National network of > 60 hospitals and cancer centres with over 930 referring clinicians.
- Established real-world data infrastructure and the largest database linking genomic and clinical data for Australian cancer patients.
- Long-term follow up process collecting clinical outcomes and health-related quality of life data with links to health resource utilisation data sources.
- Cancer Screening Program (CASP) protocol running since 2023 to underpin patient recruitment and other operational aspects.
- Experienced Molecular Oncology Board for matching therapies based on the tumour profiling result generating therapeutic recommendations.

PrOSPeCT is growing the economy and making Australia a destination for global trials:

- Over 60 industry clinical trials supported, some of which would never have reached Australia otherwise
- More than 1,200 new jobs with over $150 M AUD in direct foreign investment

Omico is a national, independent, not-for-profit organisation, uniting Australia's world-class cancer institutes, researchers, clinicians, industry partners and government like never before.

Balancing the Value and Affordability of Innovation

Science, particularly through precision oncology, has driven major advancements in cancer care, improving outcomes in non-small cell lung cancer (NSCLC) and holding similar promise for rare cancers, especially with emerging tumour-agnostic treatments (Box 1). The challenge for policy makers now is integrating these innovations into routine care through strategic investment, fair and transparent pricing that reflects the economic value of research and innovation, and targeted access models that prioritize patient outcomes without overwhelming public resources amid a diminishing taxpayer base and aging population. Failing to balance these priorities risks economic disengagement of the pharmaceutical industry, potentially hindering the on-shore commercialization of basic research and the $1.6B AUD foreign direct investment in the Australian clinical trials sector.[1] The ultimate consequence will be felt by Australian patients seeking access to life-saving medicines and their families.

Following the release of the HTA Methods Review Report in September, there has been increasing community pressure to accelerate funded access to treatments between TGA approval and PBS listing. While few can argue against the need for faster access to life-saving treatments, the issue of inequitable access and outcomes for rare cancer patients cannot be solved by focusing solely on 'bridge' funding for high-cost drugs without new approaches that address evidence gaps for rare cancers.

To avoid the pitfalls and cost overruns seen in programs like the UK's Cancer Drug Fund, healthcare reforms must be carefully implemented. While responding to community pressure for swift action is important, a data-driven strategy should guide transparent resource allocation, remaining adaptable to changing priorities through pathways for disinvestment. Special attention must be given to areas of high unmet need, ensuring equitable access for all patients without worsening disparities. These principles will ensure high-cost cancer therapies are delivered efficiently and fairly while addressing broader healthcare needs.

[1]MTPConnect. Australia's Clinical Trials Sector: Advancing innovative healthcare and powering economic growth. https://www.mtpconnect.org.au/images/MTPConnect_2024_AustraliasClinicalTrialsSectorReport.pdf (2024 Accessed 15/07/2024)

Box 1 – What is precision oncology and how is it currently accessed?

Genomic insights into cancer biology are driving drug development, with over 90% of cancer drugs in development now targeting specific molecular biomarkers.[2] Enabled by genomic tumour profiling and other technologies, precision oncology allows for patient selection, directing highly effective targeted therapies to those most likely to benefit. In NSCLC, this approach has doubled the 5-year relative survival rate and expanded therapeutic options.[3]

Currently, most access to genomic tumour profiling in Australia is either out-of-pocket or through clinical trials, limiting its use and making it harder to identify patients with rare biomarkers for effective treatments. While many therapies are approved for more common cancers, rare cancer patients can only access advanced treatments if they are suitable for a clinical trial or can pay for treatment themselves.

A major advancement is the rise of tumour-agnostic drugs which are effective across various cancer types when a relevant molecular biomarker is present.[4,5] Nine tumour-agnostic therapies are Food and Drug Administration (FDA)-approved, with more in late-phase development.[6] While these drugs are approved in Australia for specific and common tumour types, only one has been listed on the PBS in a tumour-agnostic setting, and only for a limited group of patients.

Expanding funded access to tumour-agnostic treatments for rare cancers would be groundbreaking and deliver a step change in life expectancy and care.

[2] IQVIA, 2018. Global Oncology Trends 2018. https://www.iqvia.com/insights/theiqvia-institute/reports/global-oncology-trends-2018 (2018, accessed 02/02/2022).
[3] Cancer Australia. Lung cancer in Australia statistics. https://www.canceraustralia.gov.au/cancer-types/lung-cancer/statistics (2023, accessed 26/04/2024)
[4] Brims FJ, McWilliams A, Harden SV, O'Byrne K. Lung cancer: progress with prognosis and the changing state of play. Med J Aust. 2022 Apr 18;216(7):334-4 336. doi: 10.5694/mja2.51474. Epub 2022 Mar 29. PMID: 35352375; PMCID: PMC9310756.
[5] Tateo V, Marchese PV, Mollica V, Massari F, Kurzrock R, Adashek JJ. Agnostic Approvals in Oncology: Getting the Right Drug to the Right Patient with the Right Genomics. Pharmaceuticals (Basel). 2023;16(4):614. Published 2023 Apr 19. doi:10.3390/ph16040614
[6] Gouda MA, Nelson BE, Buschhorn L, Wahida A, Subbiah V. Tumor-Agnostic Precision Medicine from the AACR GENIE Database: Clinical Implications. Clin Cancer Res. 2023;29(15):2753-2760. doi:10.1158/1078-0432.CCR-23-0090

A new approach to change the landscape for rare cancer patients

In Australia, rare cancers, including cancers of unknown primary origin, make up around 15% of all cancer diagnoses[7]. However, due to challenges in diagnosis and treatment, patients with rare cancers are more likely to die compared to those with more common cancers, representing 1 in 5 cancer-related deaths.[7] Each year, approximately 10,000 Australians lose their lives due to inequities caused by traditional drug development models and HTA processes, which limit therapeutic options and leave a high unmet clinical need.

The recent Senate Inquiry has renewed attention to the challenges faced by patients with rare cancers highlighting ongoing failures in the current healthcare system. As a high priority for cancer control, the Inquiry emphasized the need for broader access to genomic tumour profiling, timely and affordable access to novel medicines with priorities to reduce clinical trials and research disparities.

To make these recommendations a reality, new approaches are needed that involve collaboration and engagement from all relevant stakeholders: government, the health system, industry, healthcare professionals, and patients. This collective effort is essential for finding solutions that address the unique needs of patients with rare cancers and overcome systemic barriers.

Paradoxically, addressing the challenges faced by rare cancers could lead to better outcomes for all patients.

[7] *Australian Institute of Health and Welfare. Cancer data in Australia. https://www.aihw.gov.au/reports/cancer/cancer-data-in-australia/contents/about (2019, accessed 14/01/24).*

Our data shows patients benefit from precision oncology:

8 months extension of survival for those receiving an optimally matched therapy.

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A coordinated and collaborative approach to genomic profiling is key

Accelerating the use of genomic tumour profiling, which identifies multiple biomarkers in a single test, is crucial for enabling access to precision therapies. In Australia, genomic profiling is currently reimbursed only for NSCLC, using a small gene panel. By 2028, the number of drug targets for NSCLC alone is expected to reach 34, offering significant opportunities for patients. However, this growth complicates diagnosis and treatment, requiring identification based on an expanding array of biomarkers leading to increasingly smaller treatment populations. Implementing a large panel (>300 genes) approach to genomic tumour profiling in isolation is very challenging especially for the extremely rare biomarkers (Box 2).

Box 2 – Case Study: Larotrectinib

Larotrectinib was the first tumour-agnostic therapy approved by the FDA in 2017 and shows clinically meaningful responses in three out of four patients with relevant biomarkers. However, because these biomarkers are rare, present in only 0.2-1% of all cancer diagnoses, the cost of identifying patients limits cost-effectiveness for broad funded access. For example, identification of just one patient may require screening 500 patients. At a cost of $2,300 per screen this means screening costs total a cost-prohibitive c.$1.2m per patient identified for treatment.

Omico's successful approach coordinates genomic tumour profiling, directing patients to multiple therapeutic interventions as demonstrated in PrOSPeCT. By sharing the costs of genomic tumour profiling across all therapies in a coordinated program, more patients can benefit from testing, reducing the per-patient cost of selecting individuals for treatment.

The addition of PrO-HSI further improves this efficiency and we propose that the cost of screening and data collection during the program be equally shared by government and industry partners. Modelling shows that with PrO-HSI, only around 7 patients need to be screened per patient treated.

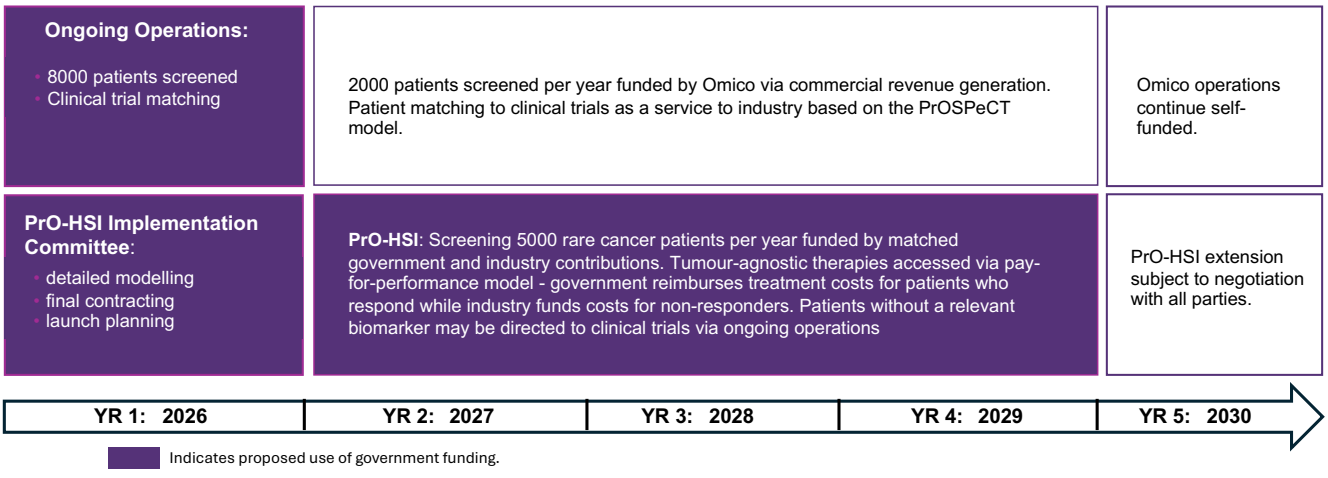
This approach will deliver efficiencies that are essential to demonstrate cost-effectiveness for broad reimbursement and the program will include a comparison across platforms to streamline implementation of a generic descriptor for technology suitable for funded access.

Omico's proven partnership model

The PrO-HSI initiative builds on Omico's existing partnership model that orchestrates collaboration and leverages investment from government and industry stakeholders (including pharmaceutical, biotechnology, diagnostics, clinical research, pathology and private hospitals and cancer care centres).

While the strength of PrO-HSI lies in strong industry participation, the program remains viable even if some parties decline. Significant engagement has already occurred, with many companies formally communicating in-principle support and a willingness to continue to progress the solution. An early commitment from the government would provide a strong incentive to formalise participation.

As outlined below, Omico proposes to coordinate a PrO-HSI Implementation Committee, consisting of government, industry, and Omico representatives. This committee would oversee the detailed design and planning, with input from experts in legal, regulatory, and other relevant government agencies, such as Cancer Australia and Australian Genomics. While Omico would coordinate some engagements between Sponsors and the Government we do not envision a role for Omico with respect to pricing negotiations or supply agreements.



Funding request

The 4-year budget outlined below bridges the funding gap during 2026 to maintain operations and supports the PrO-HSI program for three years. The government funding requested over 4 years is $115,692,529 as follows:

- Year 1 (2026): 100% allocated to ongoing operations and detailed planning and contracting for PrO-HSI. 8000 patients screened.

- Years 2-4 (2027-2030): 100% allocated to support execution of PrO-HSI. 5000 patients screened per year under PrO-HSI with an additional 2000 patients screened under ongoing operations.

The total estimated cost is ~$220 M AUD which reflects co-investment between government and industry from year 2. A 50:50 shared contribution to the cost of patient screening and data collection with a performance-based government reimbursement for treatment costs is assumed.

Total Budget ($AUD)

	Year 1	Year 2	Year 3	Year 4	Total
Screening	24,000,000	21,000,000	21,000,000	21,000,000	**87,000,000**
Long-term follow-up	-	273,750	273,750	273,750	**821,250**
Labour	11,797,500	12,151,425	12,515,968	12,891,447	**49,356,340**
Total	**35,797,500**	**33,425,175**	**33,789,718**	**34,551,940**	**137,177,590**
Omico	8,434,088	8,023,088	8,264,066	8,511,988	**33,233,506**
Drug	-	13,669,535	18,129,094	18,129,094	**49,927,723**
Total	**44,231,588**	**55,118,075**	**60,182,877**	**60,806,278**	**220,338,819**

Total public vs. private funding ($AUD)

		Year 1	Year 2	Year 3	Year 4	Total
Ongoing operations	Public	**34,231,588**	-	-	-	**34,231,588**
	Private	10,000,000	10,361,965	10,492,823	10,627,608	**41,482,388**
PrO-HSI	Public	-	**24,237,456**	**28,461,304**	**28,762,181**	**81,460,941**
	Private	-	20,518,654	21,228,750	21,416,489	**63,163,893**
	Total	**44,231,588**	**55,118,075**	**60,182,877**	**60,806,278**	**220,338,819**

Assumptions:

1. Cost definitions are as follows:
   a. Screening includes the costs per patient including the assay, other sequencing and block collection costs.
   b. Long-term follow-up costs are incurred for all patients. In year 1 these are included in the labour costs. There are additional follow-up costs associated with patients who are enrolled in a PrO-HSI therapy program. These costs are separated out for years 2-4.
   c. Labour costs refer to the labour required for patient consenting, coordination of pathology testing, matching to therapies and data collection and management.
   d. Omico costs include Omico's administrative, and personnel costs and other business costs associated with day-to-day operations.
   e. Under PrO-HSI, drug costs apply for patients treated in a PrO-HSI therapy program. Costs for responders will be reimbursed by the Government. Industry will fund supply for non-responders.
   f. Under PrO-HSI, the costs for screening, long-term follow-up and labour and a proportion of Omico costs are equally shared between Industry and Government.

2. For ongoing operations in year 1, the commercial revenue generated by Omico reflects private funding that will be reallocated to support the costs to screen additional patients in year 2-4. We anticipate funding an additional ~500-1000 patients each year.

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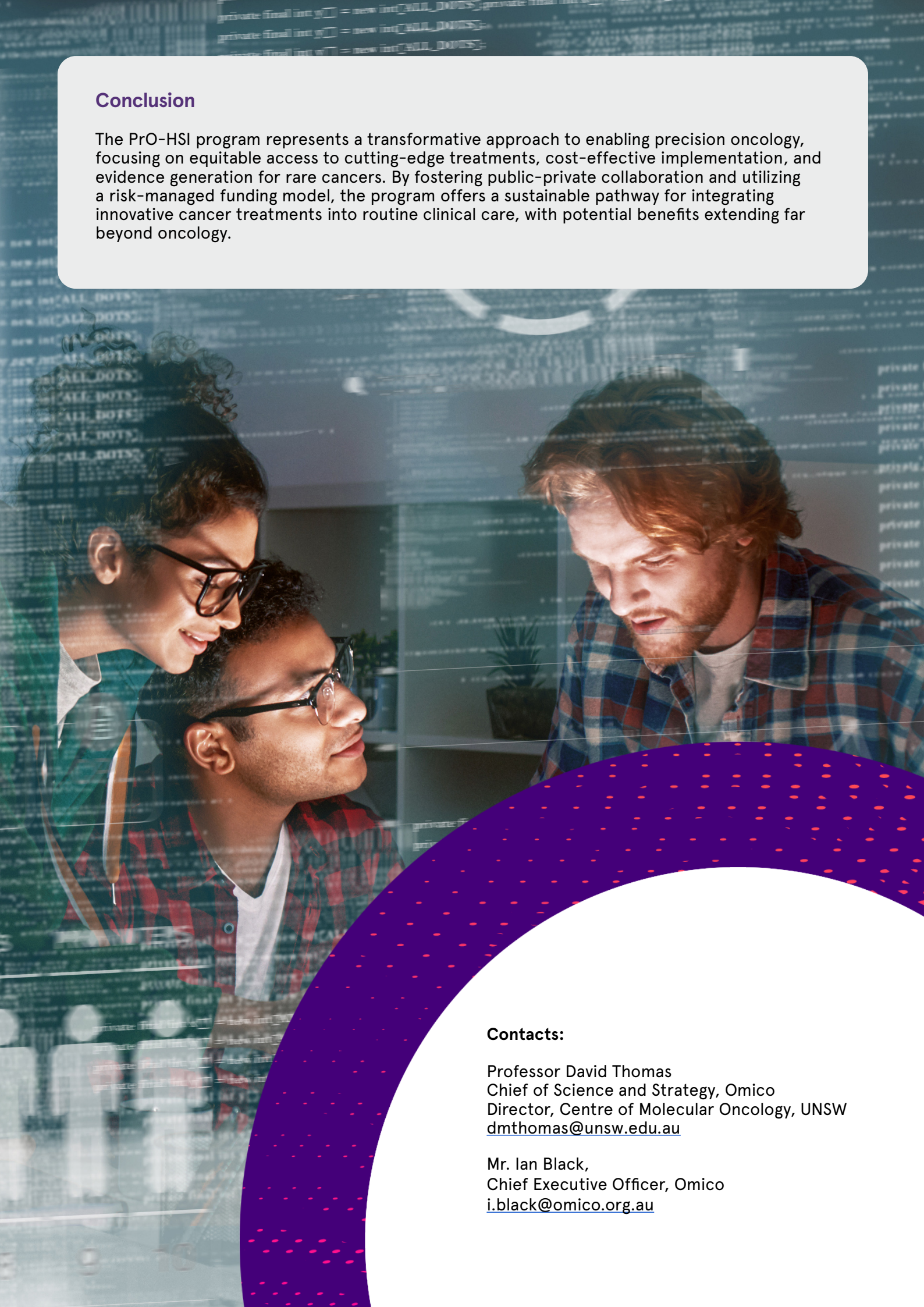
Conclusion

The PrO-HSI program represents a transformative approach to enabling precision oncology, focusing on equitable access to cutting-edge treatments, cost-effective implementation, and evidence generation for rare cancers. By fostering public-private collaboration and utilizing a risk-managed funding model, the program offers a sustainable pathway for integrating innovative cancer treatments into routine clinical care, with potential benefits extending far beyond oncology.



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