ANNUAL REPORT 2024

TOGA

Thoracic Oncology Group Australasia

REGISTERED CHARITY
acnc.gov.au/charityregister

CONTENTS

VISION

To eliminate thoracic cancers as a source of death, disability and suffering.

MISSION

To prevent, treat and cure thoracic cancers through research, clinical trials, education and advocacy.

VALUES

COURAGE

To pursue new challenges and novel solutions

INTEGRITY

To exemplify honesty and trustworthiness in all of our operations

EQUITY

To bring an open mind free of prejudice to every interaction and to strive for equal opportunity

COLLABORATION

Work with key stakeholders, organisations and community groups who share our aim of defeating thoracic cancer

CREATIVITY & INNOVATION

Strive for and be open to unique and creative solutions

STRATEGIC PLAN

Since launching our 2022-2025 strategic plan, TOGA has made substantial progress in its activities. In FY24, we have achieved the following:

POSITION TOGA AS THE LEADING AUSTRALIAN LUNG CANCER CHARITY

- Raised a total of **$197,861** within FY24.
- Supported **7 peer-to-peer campaigns** from the community and held the EOFY campaign.
- Continued growing the **Inspirational Research Grant** program to further research in thoracic oncology and the programs longevity.

BUILD A LEADING AND DIVERSE CLINICAL TRIAL AND RESEARCH PROGRAM IN THORACIC CANCERS

- Endorsed **11 research concepts** with peer and consumer reviews to raise the excellence in thoracic cancer research design.
- Facilitated **10 grant submissions** to establish a pathway for multidisciplinary TOGA researchers.
- Supported **5 clinical trials** which have opened to recruitment.
- Progressed **5 active projects** from submissions with 3 still seeking funding.

STRENGTHEN TOGA GOVERNANCE STRUCTURE

- Increased revenue by **9%** in FY24.
- Successfully awarded continued funding from the 2024-2027 Cancer Australia Support for Cancer Clinical Trials infrastructure grant.
- Commenced recruitment for a skills-based Board.

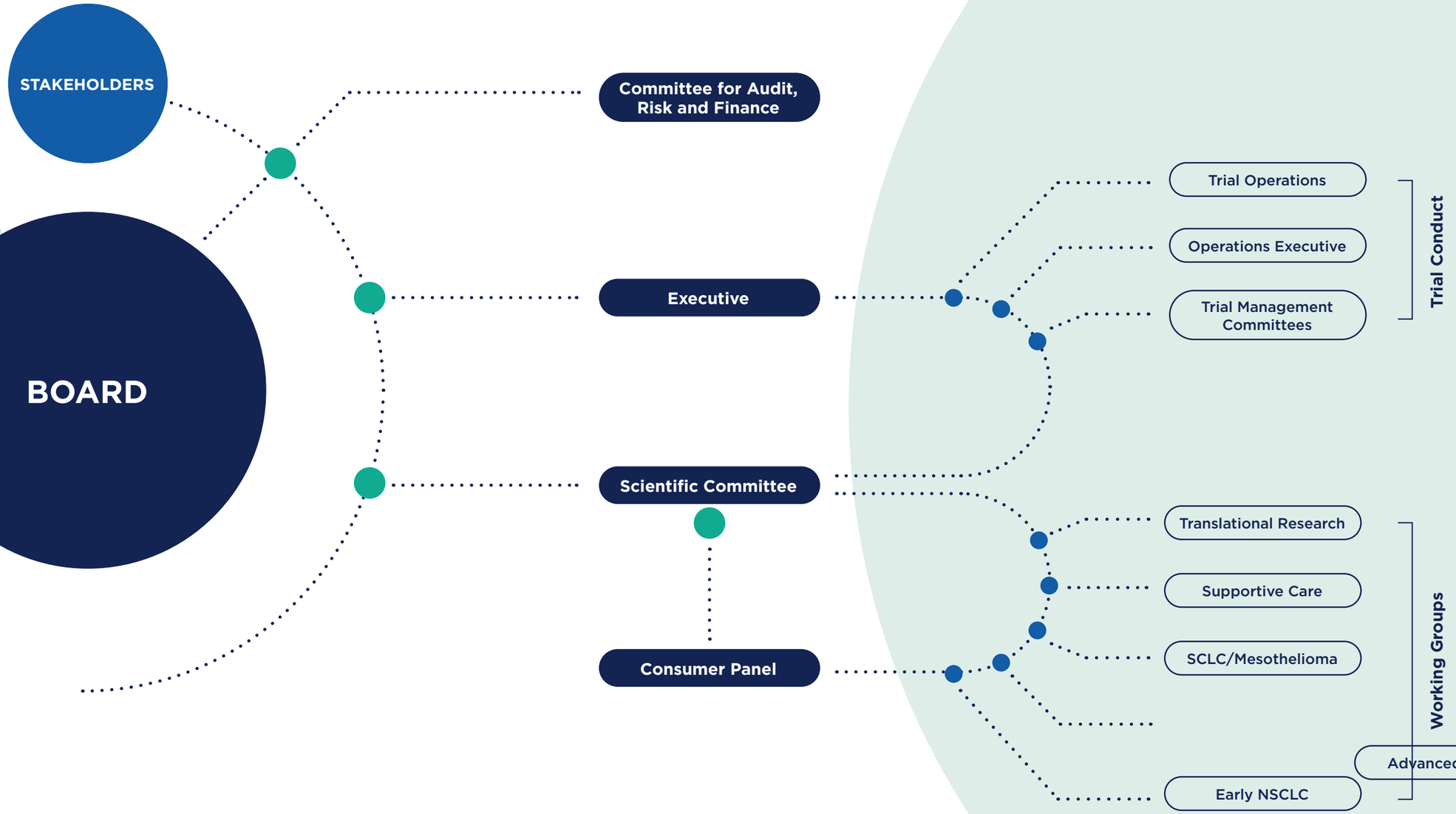
CONDUCT A HIGH-QUALITY THORACIC CANCER EDUCATION PROGRAM

- **17% YoY increase** in educational event registrations.
- Organised and coordinated **7 education events** to maintain currency with key thoracic cancer advances.
- Produced and released **10 podcast episodes**, totalling **2634 downloads** within the year.

MAXIMISE STAKEHOLDER ENGAGEMENT

- Increased partnership program by **39%** to further TOGA's mission and vision.
- Increased overall membership by **26%** with an 84% increase in Respiratory Medicine members, and 14% in Consumer Representation and Patient Advocacy.
- Organised and conducted a Lung Cancer Screening Workshop for 143 multidisciplinary attendees.

ORGANISATIONAL CHART



BOARD OF DIRECTORS

Meet the Board of Directors of the Thoracic Oncology Group of Australasia (TOGA). This group of leaders are committed to improving lung cancer outcomes through innovative research and clinical practice in Australia and New Zealand.

CHAIR

PROF NICK PAVLAKIS

BSc, MBBS, Mmed (Clin. Epi), PhD, FRACP

DEPUTY CHAIR

PROF EMILY STONE

MBBS MMed PhD FRACP

SCIENTIFIC CHAIR

PROF BEN SOLOMON

MBBS FRACP PhD

EDUCATIONAL CHAIR

A/PROF MELISSA MOORE

BA BSc MBBS (Hons) PhD FRACP

FINANCE CHAIR

CATHERINE SIM

LLB BEc FCPA MAICD

FINANCE CHAIR

PROF MICHAEL BOYER AM
(resigned 30 June 2024)

MBBS FRACP

MEMBERSHIP & ADVOCACY CHAIR

LILLIAN LEIGH

BSc LLB LLM GCHP GAICD

COMMUNICATIONS & GRANTS CHAIR

PROF SHALINI VINOD

MBBS MD FRANZCR

PHILANTHROPY CHAIR

A/PROF PHILLIP ANTIPPA

MBBS, FRACS, OAM

GOVERNANCE CHAIR

EVAN DUKAS (appointed 31 July 2024)

BBus (Acc Mar) GAICD ACPA

CHAIR'S REPORT

PROF NICK PAVLAKIS

Chair, TOGA Board of Directors

Medical Oncologist and Senior Staff Specialist
Royal North Shore Hospital and GenesisCare

BSc, MBBS, Mmed (Clin. Epi), PhD, FRACP

"Together, we will continue to drive innovation, challenge the status quo"

Prof Nick Pavlakis, Prof Myung-Ju Ahn, Dr Dasantha Jayamanne

The past year has been one of remarkable growth and progress for TOGA, reflecting our unwavering commitment to improving outcomes for people affected by thoracic cancers. As we enter our fifth year, TOGA has grown from strength to strength, now boasting 508 members—an increase from 402 at the close of FY23.

Prof Michael Boyer

Our members are the very essence of TOGA, driving high-quality treatment for thoracic cancers by providing world-class clinical education, designing and conducting innovative clinical trials, and securing competitive funding to answer the critical questions that arise in patient care.

At TOGA, we hold ourselves to the highest standards of integrity, innovation, and creativity, courage, and equity. These values underpin every initiative we undertake, ensuring that our work continues to push the boundaries of research and education in thoracic oncology. TOGA's success is a testament to the dedication and expertise of our members, who strive daily to improve patient care and advance scientific discovery.

Board and Governance Updates

This year marked significant changes in TOGA's governance. We bid farewell to Prof Michael Boyer AM, whose invaluable contributions have shaped the organisation's direction and impact. On behalf of the Board, I extend our deepest gratitude for his service and leadership. Following a rigorous external recruitment process, we were pleased to welcome Catherine Sim as Finance Director and Evan Dukas as Governance Director. In addition, Prof Emily Stone was appointed as TOGA's new Company Secretary. These appointments strengthen our governance and ensure TOGA remains well-positioned for the future.

Recognising the importance of forward-thinking leadership, the Board established a Nominations and Remuneration Committee to oversee skills assessment, succession planning for the Board, and remuneration strategies for key TOGA personnel. The Board convened eight times during FY24, reinforcing our commitment to strong governance and strategic oversight. I extend my sincere thanks to all TOGA Directors and committee members for their dedication and expertise in guiding the organisation forward.

A New Leadership Era

With TOGA's continued growth, the Board determined that the organisation required dedicated executive leadership. In line with this vision, Dr Megan Sanders, our Executive Officer, was appointed as TOGA's first Chief Executive Officer. Dr Sanders has been instrumental in shaping TOGA's trajectory, and we are confident that her leadership will drive TOGA's mission forward as we expand our impact in research and clinical education.

Sustaining TOGA's Future

Securing continued funding remains central to TOGA's ability to deliver high-quality research and education. In FY24, we successfully secured ongoing funding from Cancer Australia through the Support with Cancer Clinical Trials funding scheme, ensuring financial stability for the 2024–2027 period. This funding is a testament to TOGA's reputation for excellence in clinical trials and our commitment to addressing critical gaps in thoracic cancer research.

Recognising Excellence

TOGA members continue to be recognised for their outstanding contributions to medicine. We are proud to celebrate A/Prof Zarnie Lwin, who was awarded the Medal of the Order of Australia in recognition of her service to medicine, and Prof Haryana Dillon for the John Zalcberg Award for excellence in Research (AGITG).

Looking Ahead

As TOGA embarks on its fifth year, we remain focused on advancing research, education, and collaboration to improve outcomes for people affected by thoracic cancers. Our success is built on the dedication of our members, committees, and Board, and I thank each of you for your invaluable contributions.

Together, we will continue to drive innovation, challenge the status quo, and work towards a future where every patient receives the highest quality care.

CEO'S REPORT

DR MEGAN SANDERS
Chief Executive Officer, TOGA
PhD, CertGovNFP

"TOGA has established itself as a financially sustainable organisation, with a healthy reserve of $3.8 million"

Ellen, Dllu, Megan, Jackie

As we reflect on 2024, it is with immense pride that I present this year's achievements and the growing impact of TOGA. Our focus in 2024 was to raise awareness of TOGA's mission, enhancing our education, research, and fundraising programs, while ensuring the sustainability of our organisation. I am pleased to share that through strategic initiatives and high-performing TOGA staff and volunteers, we have made significant strides in cementing TOGA's position as the leading research charity and education provider in thoracic cancers.

ASM Audience

Raising Awareness and Enhancing Digital Presence

One of the pivotal actions undertaken in 2024 financial year was the employment of a Digital Content Manager. This role has transformed TOGA's digital presence, bringing new life to our social media platforms, newsletters, and website. The revitalised campaigns resulted in:

- Increased attendance at educational events, particularly the Annual Scientific Meeting (ASM), which saw an impressive 41% increase in attendance compared to 2023.
- A surge in podcast listenership, allowing our educational content to reach a broader audience.
- A 26% growth in membership and continuing complimentary feedback on the value of TOGA's programs.
- An average of 65% in membership newsletter open rates reflecting higher relevance and quality in our communications.
- A 51% open rate for donor newsletters, well above the industry average of 21.3%.
- A 94% increase in average donation amount, significantly bolstered by campaigns and events conducted by those in our membership who are living with lung cancer.
- Continuing high-quality research idea submissions, with 77% of grant applications submitted successfully funded.

Sustainability and Financial Health

In just four-years of operation, TOGA has established itself as a financially sustainable organisation, with a healthy reserve of $3.8 million. This financial foundation ensures our ability to continue driving critical research and education initiatives while navigating challenges in the years to come.

Advancing Research and Education

TOGA remains at the forefront of research funding for lung cancer, thymoma, and mesothelioma. Despite thoracic cancers being the leading cause of cancer death, dedicated funding for these cancers lags behind other high-profile cancers. Our work is addressing this imbalance by:

- Supporting innovative research to tackle challenges such as the lack of biomarkers for predicting therapy response.
- Highlighting limitations in the use of efficacious therapies, such as the "once-in-a-lifetime" rule for immunotherapy, which restricts treatment options for many patients.
- Translating advances in research through our robust education program for healthcare professionals (HCPs), ensuring that cutting-edge knowledge benefits patients directly.

Challenges Ahead

While our achievements in 2024 have been substantial, significant challenges persist. To address these, TOGA will focus on:

- Advocating for increased dedicated funding for thoracic cancer research.
- Driving the development and implementation of biomarker research to further personalise treatments.
- Addressing the systemic and logistical hurdles that limit the widespread implementation of efficacious treatments and diagnostics.
- Collaborating with our multidisciplinary and patient membership to ensure continuing high-quality research and best practices in thoracic cancer care.

A High Performing Team

As we move into 2025 and beyond, TOGA's vision remains clear: to lead the way in thoracic cancer clinical research and education. Our progress in 2024 demonstrates the power of collaboration, innovation, and resilience, and would not be possible without the contributions of TOGA staff, Dilu Uduwela (Events Manager), Jackie Nguyen (Digital Content Manager), Ellen Gilchrist (Administration Assistant), and Zoran Boskovic (Scientific Research Officer until January 2024).

I extend my heartfelt thanks to our Board of Directors, committee and general members, supporters and sponsors, who all make our mission possible. Together, we remain committed to improving outcomes for those affected by thoracic cancers and addressing the challenges that lie ahead.

MEMBERSHIP REPORT

508

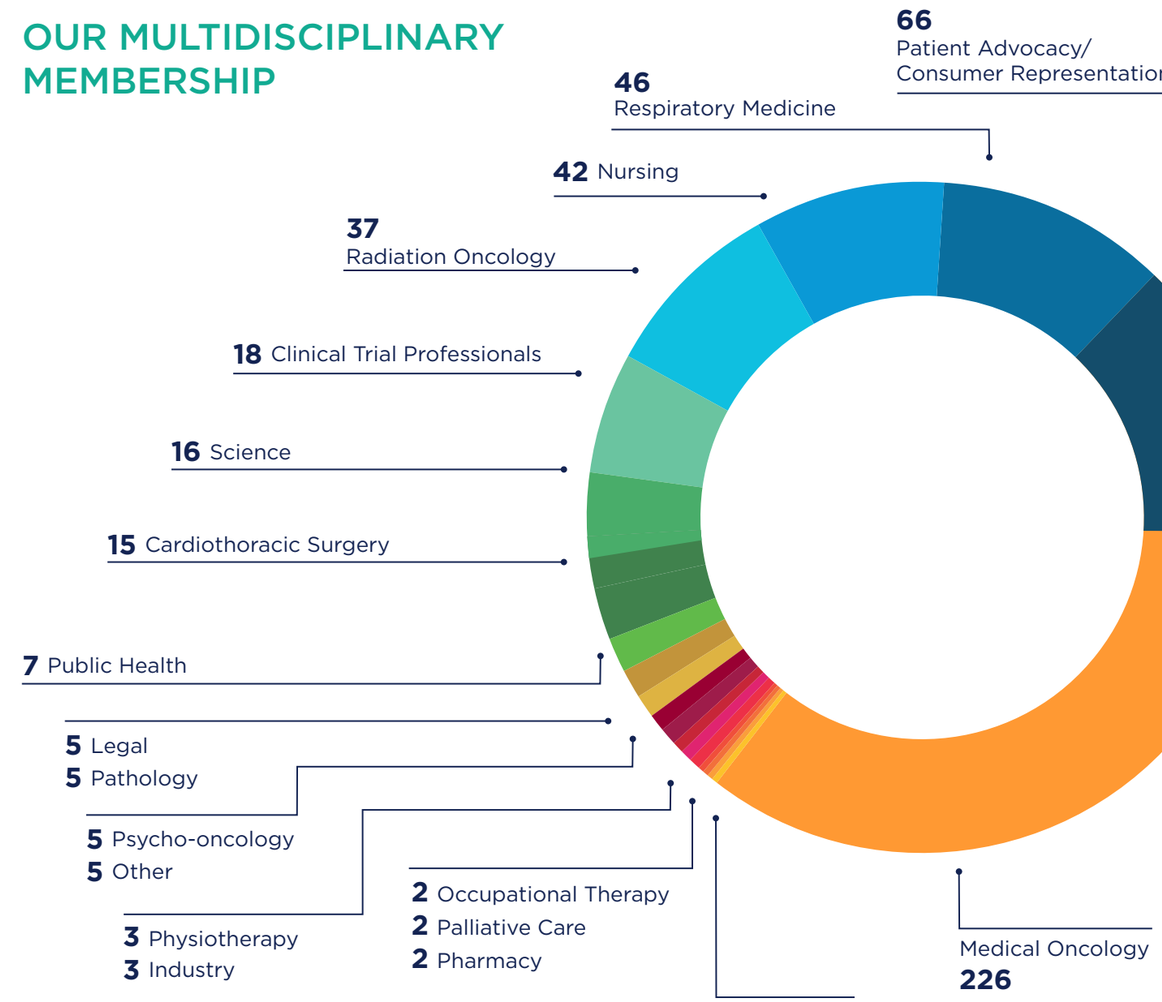
TOGA Members

*All data is collected up to June 2024

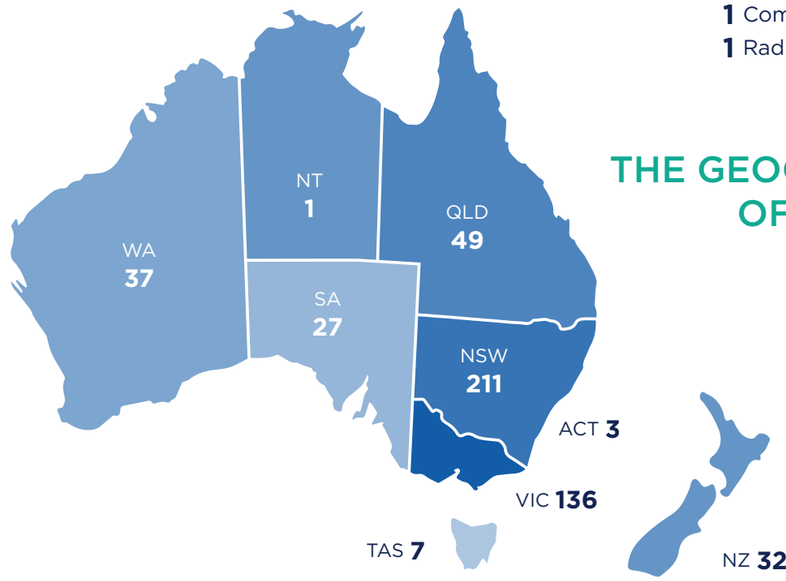
“I was searching for a professional group where I could connect with people who work towards the same outcomes and goals, and that is what TOGA has provided for me.”

Dr Tracy Leong

OUR MULTIDISCIPLINARY MEMBERSHIP



THE GEOGRAPHICAL REACH OF OUR MEMBERSHIP



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VIETNAM **1** USA **2**

FINANCE REPORT

CATHERINE SIM

Finance Chair, TOGA Board of Directors

LLB/Bec, FCPA

“Since its inception in 2020, TOGA has grown from strength to strength as an organisation”

Since its inception in 2020, TOGA has grown from strength to strength as an organisation.

For the financial year ending 30 June 2024, TOGA reported a net surplus of $972,505. The Balance Sheet posted a Retained Earnings of $3,804,142. These financial statements have been independently audited to ensure they give a true and fair view of TOGA’s financial position. The strong results are very encouraging. It demonstrates TOGA’s ongoing ability to operate in a financially sustainable manner to support our mission and strategic objectives in future years.

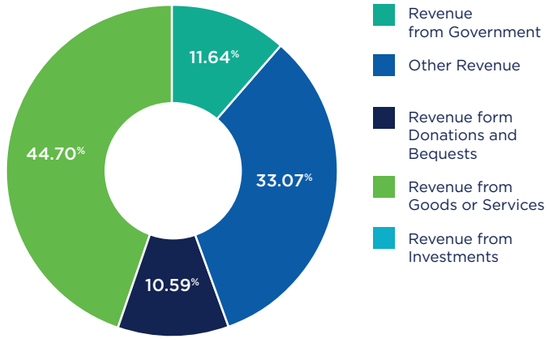
In FY24, TOGA achieved a total revenue of $1,867,819 comprising of event sponsorship, member fees, donations and fundraising and grant and trial income. Our surplus of $972,505 for FY24 is similar to FY23 surplus of $961,172. The ability to sustain a consecutive surplus has enabled TOGA’s management and board to make strategic decisions to grow the organisation in a sustainable fashion. One of the decisions includes increasing staff numbers to attract new skills to the organisation while retaining corporate knowledge and maintaining growth. It is also worth noting that the surplus is instrumental in funding our ongoing programs and new initiatives, all of which are in line with the organisation’s strategic goals.

We remain committed to fiscal responsibility and transparency in our financial operations, largely through the work of the Committee for Audit, Risk and Finance (CARF). The CARF convened for seven meetings throughout the financial year to look at financial management of the organisation and address routine matters. A routine meeting may include assessments of cash flows and financial controls, scrutiny of business and operational risks, and a thorough examination of both management and statutory accounts. Additionally, the committee conducted an in-depth analysis of the financial aspects related to proposed activities, culminating in recommendations presented to the TOGA Board of Directors. We will continue to explore opportunities for revenue diversification, strategic investment of funds and cost optimisation to ensure the long-term sustainability.

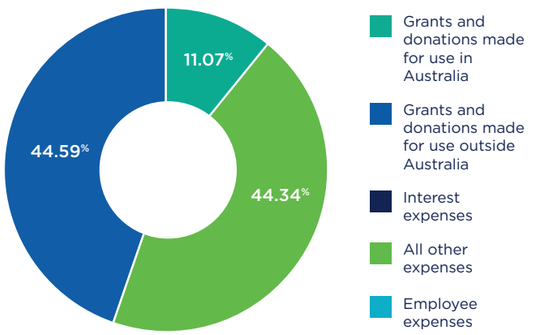
Finally, I would like to acknowledge and thank Prof Michael Boyer AM who has led the role of the Finance Chair for the last few years. Due to his leadership and passion for TOGA, he has set up a strong governance structure to promote transparency, accountability and careful management of funds. This has greatly contributed to the future financial sustainability of TOGA, its ability to maintain stability as well as providing for the future. The current CARF members and I are committed to continuing Prof Boyer’s work. I would also like to thank CARF members Prof Nick Pavlakis, Prof Emily Stone, Anita McGrath, Evan Dukas and Dr Megan Sanders (TOGA CEO) for their commitment, expertise and support. It is a great privilege to be part of such a wonderful team.

FY24 REVENUE AND EXPENSES

REVENUE
Total revenue: $1,867,819.00

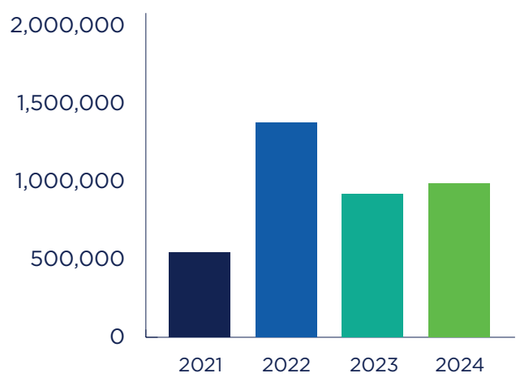


EXPENSES
Total expenses: $895,314.00

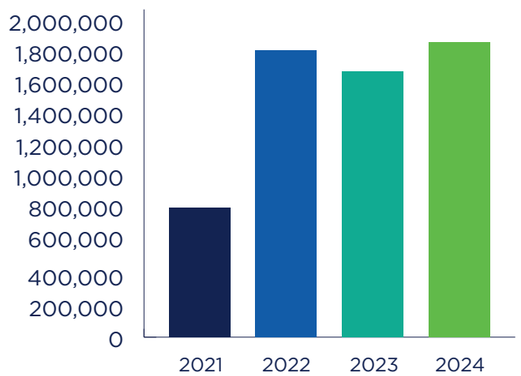


FINANCIAL PERFORMANCE OVER THE YEARS

SURPLUS FY21-24



REVENUE FY21-24



EDUCATION REPORT

A/PROF MELISSA MOORE

Education Chair, TOGA Board of Directors

Medical Oncologist St Vincent's Hospital Melbourne

BA, BSc, MB BS (Hons), FRACP, PhD

The 2024 TOGA Education Program saw ongoing increases in participation across a wide variety of events. The Education Program comprises the Annual Scientific Meeting (ASM), podcast series, Preceptorship, Micro-Satellite Symposia and post-international meeting webinars.

Prof Phil Crosbie, Dr Jessica Donington, Prof Myung-Ju Ahn

The ASM was held in Sydney with the theme *"Charting New Horizons: A Multidisciplinary Approach to Lung Cancer Screening and Care"*. The multi-disciplinary meeting was convened by Dr Tracy Leong and Dr Maggie Moore who were ably supported by an engaged local organising committee. There were 418 in person attendees which is a significant increase in attendance compared to 2023. This highlights the increasing profile of TOGA and its place as the premier information source for those involved in thoracic malignancies. There were three outstanding international speakers - Dr Jessica Donington (Professor of Surgery and Chief of the Section of Thoracic Surgery, University of Chicago), Prof Myung-Ju Ahn (Professor, Department of Medicine, Sungkyunkwan University School of Medicine, Seoul) and Prof Philip Crosbie (Senior Lecturer and Honorary Consultant in Respiratory Medicine, University of Manchester). Prof Crosbie presented on the Manchester experience of implementing lung cancer screening which was of great relevance to the Australian audience and the theme of the ASM.

The ASM also provided an opportunity for new data to be presented with all disciplines contributing. The ASM 2024 TOGA New Investigator Award went to Dr Peter Shi, Post-Doctoral Fellow, Asbestos and Dust Diseases Research Institute and the ASM 2024 TOGA Best Poster Award went to Dr Amelia Parker, Senior Research Officer, Garvan Institute of Medical Research.

A standalone workshop on lung cancer screening was held prior to the ASM. This aimed to provide overview of the progress in the National Lung Cancer Screening Program (LCSP) implementation. This was attended by 143 participants across a wide range of disciplines and provided all with the opportunity to be updated on the implementation process as well as discuss challenges.

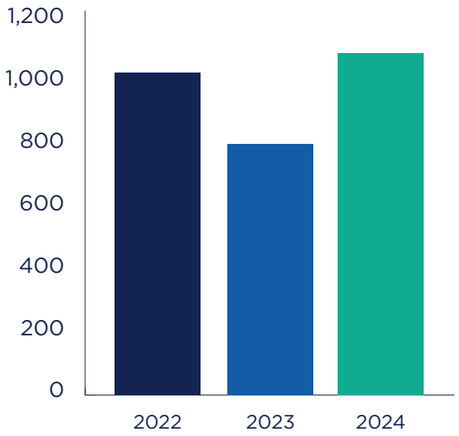
The podcast series continues to grow and involves a diverse range of speakers from across the thoracic malignancy community. The number of listeners increases year on year. For 2024, the podcast with the highest number of listeners was *"Lung Cancer Nurses: Essential, Beneficial and a Key Link in Lung Cancer Screening".* This reflects the interest in lung cancer screening but also highlights the importance of multi-disciplinary care and lung cancer nurses.

The annual Preceptorship was held in Brisbane this year with 67 attendees. 40 preceptees critically appraised pivotal data in thoracic malignancies. The event was enjoyed by both preceptors and preceptees. Not only is it a critical opportunity to be updated on data but also provides opportunities for informal networking between preceptees and preceptors in a relaxed and supportive environment.

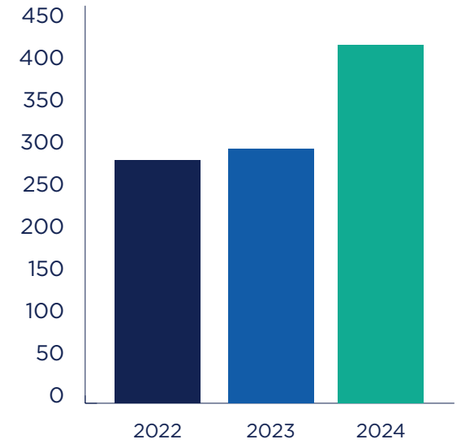
The education program would not be possible without the generous support of our sponsors. We thank them for their role in helping TOGA provide a wide-ranging, multi-disciplinary program for all involved in the provision of quality care to people living with thoracic malignancies.

Prof Wendy Cooper, A/Prof Melissa Moore

OVERALL EVENT ATTENDANCE



ASM ATTENDANCE



Lillian Leigh

Dr Matthew Cockcroft, Dr Claudia Leslie, Dr Alexandra Schuler

Dr Dasantha Jayamanne

Dr Yifei (Faye) Zhu, Dr Ria Nadakkavukaran, Dr Claudia Leslie

Dr Lyn Ley Lam, Dr Nicholas Yeo, Dr Elizabeth Driscoll, Dr Deborah Zhou

Dr Annie Wong, A/Prof Thomas John

A/Prof Steven Kao, Prof Ben Solomon, A/Prof Thomas John, Dr Jessica Donington

Prof Nick Pavlakis, Prof Christopher Cao, Jon Graftdyk, Dr Tracy Leong, Prof Philip Crosbie, Dr Jessica Donington, Prof Myung-Ju Ahn, Dr Maggie Moore, A/Prof Melissa Moore, Dr Fiona Hegi-Johnson, Prof Haryana Dhillon

PHILANTHROPY REPORT

A/PROF PHILLIP ANTIPPA OAM

Philanthropy Chair, TOGA Board of Directors

Cardiothoracic Surgeon
The Royal Melbourne Hospital/
Peter MacCallum Cancer Centre

MBBS, MPH, FRACS

Dr Lauren Gray

Our financial year 2024 fundraising efforts demonstrated continued community support, raising $197,861. These funds directly fuel our mission to combat thoracic cancer through research, education, and advocacy.

The 2024 End of Financial Year (EOFY) campaign achieved remarkable success, raising $40,688.75. This year's campaign powerfully highlighted the inspiring story of Angeline Low, who *"is alive today thanks to [her] medical team, lung cancer researchers, clinical trials, and new treatments."* Her story serves as a poignant reminder of the life-saving impact of our research and the crucial role of community support.

Our peer-to-peer fundraising initiatives continued to thrive in 2024, with seven successful campaigns launched throughout the year.

Natalie Dubbs, a Stage 4 ALK+ lung cancer survivor, celebrated the ten-year anniversary of her diagnosis with her campaign "Living Proof", raising over $16,183 for DYNAMALK. This campaign powerfully demonstrated that with the right testing, medicine, and knowledgeable clinical management, patients' lives can be significantly extended with an excellent quality of life, inspiring hope and emphasising the importance of ongoing research.

Friends and family of Louise Kuchel, who battled a rare type of lung cancer, gathered to celebrate her life and raise over $3,400. This touching tribute to Louise, with entertainment from a cover band led by her dear friend Maxine Rickman, underscores the importance of community support in honouring the lives of those affected by thoracic cancer.

Rohit Sharma, our dedicated runner and person living with lung cancer, led a successful fundraising effort through a half-marathon raising $1,848.50. Go Rohit!

The campaign honouring the life of Mike Faulkner, a beloved husband and father, raised $6,593. This campaign serves as a poignant reminder of the impact that cancer has on families and the importance of supporting research to prevent future losses.

Lastly, our ongoing DYNAMALK campaign continued to make significant strides, surpassing $25,436.

Building upon the success of previous years, we are continually exploring innovative fundraising strategies to maximise our impact. We are grateful for the unwavering support of our donors and community partners. Together, we remain dedicated to advancing thoracic cancer research, improving patient outcomes, and ultimately finding a cure for this devastating disease through programs such as the Inspirational Research Grant.

Louise Kuchel and family

Angeline Low

NATALIE DUBS

LIVING PROOF: ADVANCING LUNG CANCER RESEARCH TOGETHER

Natalie Dubs passed her 10th cancer anniversary in May 2024. It's a significant milestone for any person living with lung cancer. Natalie is living proof that with research, the right testing and available medicine together with knowledgeable and well-resourced clinical management lung cancer with brain metastases can be treated to become a chronic disease which extends patients' lives with excellent quality of life.

Natalie and Michael Dubs

Thanks to advancing clinical research and clinical trials as well as Natalie's oncologist's forefront knowledge in lung cancer treatment, she has been living well while managing the sides effects caused by successive treatments for NSCLC medicine that she has been through. While making adjustments in daily life where needed, and with her husband's and family's support, living with cancer hasn't stopped Natalie from doing what she wants to do. Natalie has experienced various jobs that she wanted to try; bought a unit and renovated it; got a cheeky dog named Taicho as well as travelled overseas for holiday many times. Since diagnosis Natalie has also found many hobbies that she enjoys very much and is still doing everyday. There's a proverb that helps her everyday: "to get through the hardest journey we need take only one step at a time, but we must keep on stepping."

Six years ago, Natalie had a brain surgery and donated her resected brain tumour to research in order to help comparative studies into testing and resistances to medication developed over time. This testing showed that with the comprehensive genomic information, the best medicine, if available, can be selected.

Natalie's wish is for "everyone going through this disease to have an opportunity to live their life, conquer their dreams, have more time with their loved ones, build a family or grow old with their families."

Research has given Natalie 10-years of life and she knows that inspiring clinical research is the key to saving lives.

THE INSPIRATIONAL RESEARCH GRANT

At TOGA, our leading priority is conducting research to advance knowledge, practice, and education in thoracic oncology. The Inspirational Research Grant allows us to further knowledge in thoracic oncology to work towards integrating them into routine healthcare procedures.

In the second year the Inspirational Research Grants have been awarded, two recipients will be awarded $50,000, with the funding to be used over a two-year period.

Additionally, TOGA has partnered with ALK Positive Australia Inc. to create one grant dedicated to advancing ALK+ NSCLC research in Australia.

The 2025 Grant Recipients

This year's grant recipients will be furthering research in projects defining lung cancer microbiome and genomic diversity in ALK positive NSCLC. Here are your 2025 Inspirational Research Grant recipients:

Dr Mark Adams
CGRA Senior Research Fellow, Cancer Genomics Program Lead, Centre for Genomics and Personalised Health, Queensland University of Technology

Pioneering lung cancer microbiome research in Australia: standardising sequencing, bioinformatic analysis and clinical associations between interstate institutions.

This research will focus on metagenomic sequencing to accurately map the lung microbiome's taxonomic and functional makeup. This microbial profile will then be examined in relation to treatment responses, assessing whether the lung microbiome contributes to treatment outcomes.

Dr Sagun Parakh
Medical Oncologist and Clinician Scientist, Olivia Newton John Cancer Research Institute, Austin Hospital

A study to evaluate the impact of the lung microbiome on the efficacy and toxicity of immunotherapy in lung cancer patients.

This research delves into the taxonomic and functional composition of the lung microbiome to understand the correlation with the development of immune-mediated adverse events. This will determine if the lung microbiome plays a role in development of toxicity to immunotherapy treatment.

A/Prof Venessa Chin
Medical Oncology, The Kinghorn Cancer Centre, St Vincent's Hospital Sydney; Post-doctoral Research Officer, The Garvan Institute of Medical Research

ALK POSITIVE AUSTRALIA

Unravelling Genomic Diversity in ALK-Positive Non-Small Cell Lung Cancer: Insights from Paired RNA/DNA Sequencing of Circulating Tumour Cells.

4% of lung cancers are caused by a genetic change in the gene called 'ALK'. Although these cancers can respond well to targeted therapies, treatment resistance is inevitable. Using a novel technology "AccuCyte-CyteFinder", we can extract cancer cells from blood samples taken from patients with ALK positive lung cancer. This next frontier in "liquid biopsies" has the potential to aid in diagnosis, guide therapy selection, prognosis, predict treatment resistance and monitor treatment effects in real-time.

This project employs a novel, new and ultrasensitive method to examine cell clones that may be present at diagnosis of ALK+ metastatic NSCLC.

We would like to thank all the members, ALK Positive Australia Inc. and supporters for their efforts in raising the funds to make the Inspirational Research Grant possible.

SCIENTIFIC PROGRAM REPORT

PROF BEN SOLOMON

Scientific Chair, TOGA Board of Directors

Medical Oncologist
Peter MacCallum Cancer Centre

MBBS, PhD, FRACP

“With continued input from our membership and consumer groups, we are committed to advancing thoracic oncology research and delivering meaningful improvements in patient outcomes”

TOGA Patient Advocates

In 2024, the TOGA Scientific Committee, under the leadership of Prof Thomas John, continued its important work through rigorous consumer and peer reviews of research concepts and overview of our research portfolio. These efforts were facilitated by four Scientific Committee meetings and seven Working Group meetings. Throughout the year, sixteen research concepts were reviewed, with eleven receiving endorsement and advancing to further development, including applications for funding.

The development and conduct of clinical trials remain at the core of TOGA’s mission. Our flagship national trial, **ASPiRATION**, which achieved its target accrual in 2023, continued to progress with patients receiving treatment across four arms of the MoST study and ongoing follow-up. This trial has demonstrated the value of molecular testing in non-small cell lung cancer (NSCLC) and our capacity to implement this on a national scale, including in regional and rural areas via telehealth.

Building on this success, the team is developing a follow-up study, **ASPiRATION 2-Liquid**, which uses ctDNA testing to guide therapy. A grant application for this study was submitted in 2024, and we eagerly await the outcome.

Other key trials also made significant strides-

We continue recruiting patients for the **SHERLOCK** (PI: Prof Chee Lee) and **OCEANIC** studies (PI: Prof. Thomas John). Notably, the OCEANIC study is testing a novel paradigm that utilises ctDNA to potentially de-intensify adjuvant treatment for early-stage EGFR mutation-positive NSCLC. These advancements underscore the critical role of clinical research participants, whose contributions are invaluable to the advancement of thoracic oncology. We also acknowledge our partners, including the NHMRC Clinical Trials Centre U/Syd, for their ongoing collaboration.

The **DYNAMALK** trial conducted by Dr Malinda Itchins and supported by a fundraising campaign spearheaded by TOGA consumer representatives opened to recruitment. The study offers serial real time genetic profiling in ALK+ NSCLC to determine if provision of this information changes treatment decisions, or if a particular treatment changes the genomic environment leading to resistance.

DREAM3R, a phase 3 trial of durvalumab with chemotherapy as first line treatment in mesothelioma, continues with recruitment closing at 214 participants.

The **OSCILLATE** trial investigating alternating cycles of a novel targeted therapy and standard-of-care treatment in patients with ALK-positive or EGFR-positive non-small cell lung cancer (NSCLC) published in 2024. While the alternating regimen demonstrated a favorable safety profile and was well-tolerated, it did not significantly delay the development of resistance. Importantly, accompanying translational research provided valuable insights into resistance mechanisms, revealing their heterogeneity and suggesting the involvement of pathways beyond simple oncogene escape variants.

This year, we express our sincere gratitude to our outgoing Working Group Chairs:

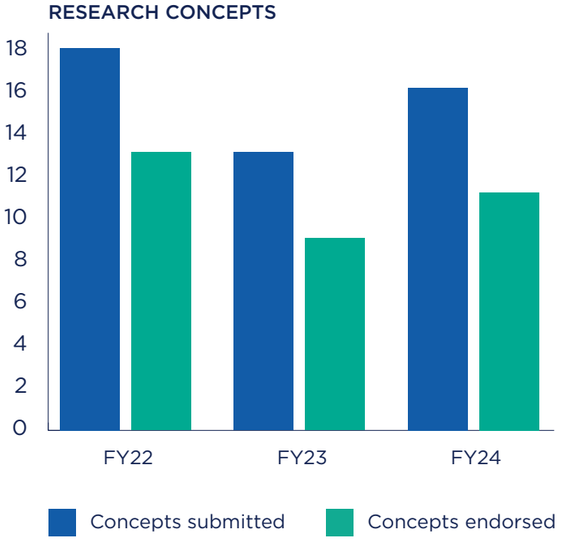
- A/Prof Steven Kao (SCLC/Mesothelioma)
- Dr Michael Harden (early NSCLC)
- Prof Fraser Brims (early NSCLC)

Additionally, we thank committee members Prof. Michael Millward, Susan McCullough OAM, and Anita McGrath, for their dedicated service.

We warmly welcome our new chairs, Dr Tracy Leong (early NSCLC), A/Prof Surein Arulananda (SCLC/Mesothelioma), and A/Prof Gavin Wright (early NSCLC), along with new committee members Dr Joe Wei, Alison Bolton, John Graftdyk, and Teresa Faé. Their expertise will be instrumental in driving our future efforts.

We also extend our thanks to the Consumer Panel for their valuable input and welcome new members Martin Cumming, Peter Young, Peter Spolc, Carly Magnisalis, Teresa Faé, Jon Graftdyk and Graham Hall.

Looking ahead to 2025, we anticipate the implementation of the National Lung Cancer Screening Program, which promises to improve lung cancer survival rates and open new avenues for clinical trials. With continued input from our membership and consumer groups, we are committed to advancing thoracic oncology research and delivering meaningful improvements in patient outcomes.



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Medical Oncologist
Peter MacCallum Cancer Centre

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Medical Oncologist and Senior Staff Specialist
Royal North Shore Hospital and GenesisCare

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Deputy Director Medical Oncology
Monash Health

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Palliative Medicine and Oncology Specialist
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Early Career Researcher Representative
Dr Rachael Dodd
Senior Research Fellow
The Daffodil Centre

Scientific Representative
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Medical Oncologist
Scientia Clinical Research

Scientific Committee Member
Dr Vanessa Brunelli
Research Fellow
Queensland University of Technology

Clinical Lung Cancer Nurse
Helen Westman
Lung Cancer Nurse Consultant
Royal North Shore Hospital

Lung Lead - NHMRC CTC
A/Prof Chee Khoon Lee
Medical Oncologist and Senior Staff Specialist
St George and Sutherland Hospitals

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Patient Advocate

Consumer Representative
Alison Bolton
Patient Advocate

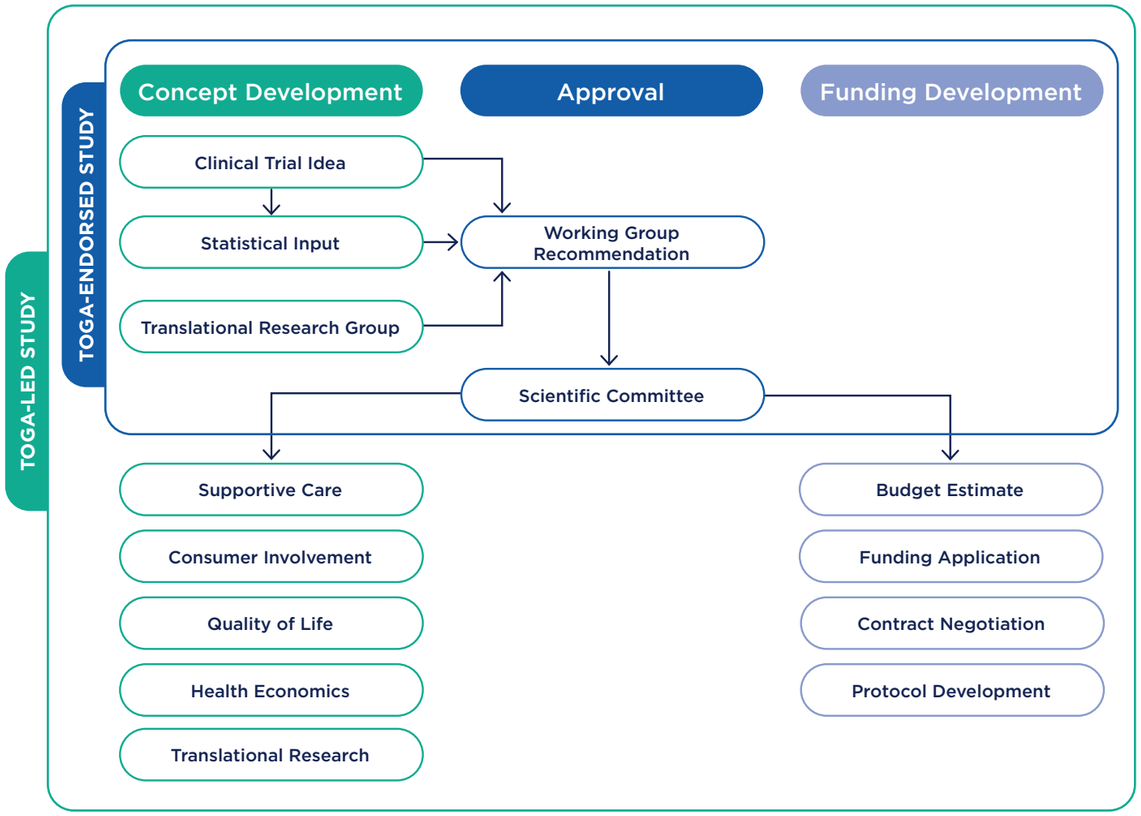
Consumer Representative
Lisa Briggs
Patient Advocate

Clinical Lung Cancer Nurse
Amy O'Donnell
Lung Cancer Nurse Specialist
Chris O'Brien Lifehouse

Biostatistician - NHMRC CTC
Chris Brown
Biostatistician and Research Fellow NHMRC Clinical Trials Centre (CTC), University of Sydney

Consumer Representative
Jon Graftdyk
Patient Advocate

RESEARCH DEVELOPMENT PATHWAY



CONSUMER PANEL MEMBERS

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Teresa Faé
Patient Advocate

Consumer Panel Deputy Chair
Alison Bolton
Patient Advocate

Anita McGrath
Patient Advocate

Carly Magnisalis
Patient Advocate

Graham Hall
Patient Advocate

John Cannings
Patient Advocate

Jon Graftdyk
Patient Advocate

Lisa Briggs
Patient Advocate

Martin Cumming
Patient Advocate

Peter Spolc
Patient Advocate

Peter Young
Patient Advocate

Susan McCullough OAM
Patient Advocate

Susan McCullough OAM

CLINICAL TRIALS

TITLE: SHERLOCK

Phase 2 trial of sotorasib in combination with carboplatin-pemetrexed and bevacizumab biosimilar as first line treatment for advanced non-squamous NSCLC with KRAS G12C mutation

CLINICAL TRIAL DESIGN:
Single-arm, phase 2 study with a safety run-in

INDICATION:
Newly-diagnosed or recurrent metastatic non-squamous NSCLC with KRAS G12C mutation (treatment naive for advanced disease)

INTERVENTION:
All participants enrolled in this clinical trial will begin with Induction therapy of Sotorasib 960mg oral once daily, together with Carboplatin-Pemetrexed chemotherapy and Bevacizumab on day 1 every 3 weeks for 4 cycles.

SUMMARY:
The purpose of the study is to test the effectiveness of a new treatment combination for patients with NSCLC whose tumour has a specific type of gene mutation called KRAS G12C. This mutation is believed to cause the tumour to grow and spread. This study will investigate whether sotorasib used in combination with two chemotherapy drugs (called carboplatin and pemetrexed) and bevacizumab (which improves anti-cancer drug delivery), is well-tolerated, shrinks the tumour, delays relapse and provides longer and better quality of life.

RECRUITMENT TARGET:
52

STATUS:
Open to recruitment

TITLE: OCEANiC

Osimertinib plus Chemotherapy Evaluation in Adjuvant NSCLC incorporating CtDNA.

CLINICAL TRIAL DESIGN:
Phase II, open-label, multi-centre clinical trial

INDICATION:
Patients with Stage IIA-IIIA EGFR-Mutant NSCLC following complete surgical resection.

INTERVENTION:
All participants receive osimertinib 80 mg orally, once daily, for up to 3 years or until disease recurrence, unacceptable toxicity or consent withdrawal, whichever is sooner. Cohort 2 participants also receive 4 cycles of chemotherapy.

SUMMARY:
Treatment of local or locally advanced NSCLC with a mutation within the EGFR gene, has evolved to include osimertinib in addition to standard of care chemotherapy and possibly, radiotherapy. The benefit of osimertinib has been found to be so profound in this group of patients that this study will investigate whether patients containing certain types of genetic signatures can be treated with osimertinib alone without chemotherapy. Positive findings may provide evidence for similar benefits for using the drug alone, with less toxicity, improved quality of life and reduced health care costs.

RECRUITMENT TARGET:
100

STATUS:
Open to recruitment

Trial status correct as at 6 March 2025

CLINICAL TRIALS

TITLE: DYNAMALK
ALK+ NSCLC: an Australian Dynamic ctDNA Profiling Study

COLLABORATION WITH:
AURORA

CLINICAL TRIAL DESIGN:
Multi-centre, prospective non-interventional cohort study

INDICATION:
ALK-mutation positive NSCLC planned to initiate lorlatinib directly as next line of therapy as per Investigator's discretion

INTERVENTION:
Collection of blood for real time ctDNA analysis at baseline, 6-12 weeks and 18 months

SUMMARY:
DYNAMALK aims to undertake molecular profiling via an Australian ctDNA study in treatment naïve and pre-treated ALK+ NSCLC patients to describe and correlate ctDNA findings according to any prior therapies and temporal genomic profiles of patients recruited, to identify patterns of emerging resistance against clinical outcomes, and to report the influence of ctDNA genomic data obtained real time in informing clinical management over and above standard of care.

RECRUITMENT TARGET:
30

STATUS:
Open to recruitment

TITLE: ASPECT
Functional lung Avoidance SPECT-guided (ASPECT) radiation therapy of lung cancer

CLINICAL TRIAL DESIGN:
Randomised double-blinded prospective phase II clinical study with 2:1 randomisation.

INDICATION:
Stage II to IV cancer patients undergoing radiation therapy with curative intent.

INTERVENTION:
SPECT functional avoidence during treatment with radiotherapy.

SUMMARY:
The aim is to establish the rates of radiation-induced lung disease outcomes, quality of life, and progression-free survival in lung cancer patients treated with Functional avoidance radiotherapy (Arm 1) and Standard radiotherapy (Arm 2).

RECRUITMENT TARGET:
195

STATUS:
Open to recruitment

Trial status correct as at 6 March 2025

TITLE: METASTATIC NSCLC SURVIVORSHIP MDT STUDY
Enhancing Survivorship Care For Long-Term Responder Patients with Metastatic Non-Small Cell Lung Cancer (mNSCLC): Feasibility of a Multi-Disciplinary Team (MDT) Consultation

CLINICAL TRIAL DESIGN:
Phase 1, single-arm, prospective mixed-methods cohort study.

INDICATION:
Adults with unresectable or metastatic NSCLC with evidence of >6 months without disease progression who have undergone systemic therapy.

INTERVENTION:
A one-off virtual MDT consultation to identify and address the survivorship needs of long-term responder patients with mNSCLC.

SUMMARY:
This clinical trial evaluates the feasibility and acceptability of a virtual MDT consultation for long-term responder patients with mNSCLC. The study aims to enhance communication between hospital-based cancer teams, primary care providers, and patients to address survivorship challenges, such as chronic toxicity, psychological concerns, and practical needs.

RECRUITMENT TARGET:
30

STATUS:
In follow up

TITLE: DREAM3R
DuRvalumab (MEDI4736) with chEmotherapy as first line treAtment in advanced pleural Mesothelioma – A phase 3 Randomised trial

CLINICAL TRIAL DESIGN:
Open-label Phase III randomised clinical trial

INDICATION:
Newly diagnosed unresectable malignant pleural mesothelioma

INTERVENTION:
First-line treatment with standard chemotherapy of pemetrexed and cisplatin. Two-thirds of the participants in the study were randomly assigned to also receive durvalumab (immunotherapy).

SUMMARY:
The DREAM3R clinical trial is determining the effectiveness of adding durvalumab to standard first line chemotherapy with cisplatin and pemetrexed in advanced malignant pleural mesothelioma and identifying potential and prognostic biomarkers from blood and tissue. Durvalumab is an antibody (a type of human protein) that works by blocking a body substance called Programmed Death-Ligand 1 (PD-L1) and reawakens the immune system to recognise tumour cells. Previous studies of combining durvalumab and chemotherapy showed that this combination is active in advanced mesothelioma. During the study it became possible to access a combination immunotherapy treatment regimen of ipilimumab and nivolumab for advanced mesothelioma. Known as ipi/nivo, this combination immunotherapy is directed to other targets involved in immune recognition of tumours. The DREAM3R study underwent an amendment so the ipi/nivo treatment regimen was also allowed.

RECRUITMENT TARGET:
480 (Closed with 214 participants only due to poor recruitment)

STATUS:
In follow up

Trial status correct as at 6 March 2025

CLINICAL TRIALS

TITLE: ASPiRATION
An observational cohort study to assess the clinical impact of CGP in metastatic lung cancer patients

CLINICAL TRIAL DESIGN:
Observational cohort study

INDICATION:
Newly-diagnosed metastatic non-squamous NSCLC

INTERVENTION:
CGP to identify actionable biomarkers to guide therapy

SUMMARY:
The ASPiRATION study investigated the clinical impact of CGP on the management of metastatic NSCLC and assessed the feasibility of CGP implementation nationally. When the ASPiRATION study was open to recruitment, standard of care tumour testing for NSCLC patients could only identify changes in three genes: EGFR, ALK & ROS1. Patients enrolled on the ASPiRATION study also had their tumour tested using CGP, often referred to as molecular screening and/or profiling. This technique allowed treating clinicians to look at changes in hundreds of genes in a single test. After a patient's tumour was tested, a report was sent to the referring oncologist with information on (i) Any genetic biomarkers that were identified in the tumour and (ii) The types of treatment that may be suitable.

This research demonstrated the feasibility of integrating additional molecular screening into Australian clinical practice for patients with metastatic NSCLC.

RECRUITMENT TARGET:
1,000

STATUS:
In follow up

ASPiRATION SUBSTUDIES:
ASPiRATION substudies include NSCLC-specific substudies and MoST substudies that cater for NSCLC patients with tumours expressing the appropriate molecular biomarkers. The ASPiRATION substudies are all Phase II single arm open label signal-seeking clinical trials with the intent to demonstrate or confirm drug activity and safety in order to inform subsequent randomised Phase III clinical trials

The ASPiRATION study and substudies are led by TOGA, in collaboration with Omico (Australian Genomic Cancer Medicine Centre) and the NHMRC Clinical Trials Centre (CTC), University of Sydney.

SUBSTUDY: HER2 + NSCLC
A single-arm, open-label, phase II trial of trastuzumab emtansine in patients with metastatic NSCLC harbouring *HER2* mutations and/or amplifications detected using CGP (MoST 8)

INDICATION:
Pathologically confirmed metastatic non-squamous NSCLC harbouring *HER2* mutations and/or amplifications detected by CGP in the ASPiRATION study

INTERVENTION:
Trastuzumab emtansine, 3.6mg/kg IV q3 weeks until disease progression or unacceptable toxicity.

STATUS:
In follow up

SUBSTUDY: ALK+ NSCLC
A single arm, open label, phase II trial of alectinib in patients with advanced tumours harbouring *ALK* gene alterations detected by CGP (MoST 14)

INDICATION:
Patients with advanced cancers harbouring *ALK* gene alterations identified using CGP. NSCLC patients with *ALK* gene alterations must be FISH-negative, i.e. not eligible for reimbursed ALK-targeted treatment

INTERVENTION:
Patients will receive continuous alectinib 600 mg twice a day until disease progression, participant withdrawal or unacceptable toxicity.

STATUS:
Open to recruitment

SUBSTUDY: BRAF V600 + NSCLC
Single arm, open label, phase II trial of vemurafenib and cobimetinib in patients with advanced tumours harbouring *BRAF V600* mutations detected by CGP (MoST 12)

INDICATION:
Patients with pathologically confirmed metastatic non-squamous NSCLC or other advanced cancers harbouring a *BRAF V600* mutation detected by CGP.

INTERVENTION:
Patients will receive continuous vemurafenib 960 mg twice a day (from days 1 to 28 in a 28-day cycle) in combination with cobimetinib 60 mg daily (from days 1 to 21 in a 28-day cycle, followed by a 7-day break in cobimetinib treatment from days 22 to 28) until disease progression, participant withdrawal or unacceptable toxicity.

STATUS:
In follow up

SUBSTUDY: NTRK or ROS1
A single-arm, open-label, phase II trial of entrectinib in patients with advanced tumours harbouring *NTRK* fusions or *ROS1* gene rearrangements detected by CGP (MoST 13)

INDICATION:
Patients with advanced cancers harbouring *NTRK* fusions or *ROS1* gene rearrangements identified using CGP. NSCLC patients with *ROS1* gene alterations must be FISH-negative, i.e. not eligible for reimbursed ROS1-targeted treatment

INTERVENTION:
Patients will receive continuous entrectinib 600mg once daily orally until disease progression, participant withdrawal or unacceptable toxicity.

STATUS:
In follow up

SUBSTUDY: MET EXON 14 SKIPPING MUTATIONS + NSCLC
A single-arm, open-label, signal-seeking, phase II trial of tepotinib in patients with advanced NSCLC harbouring *MET exon 14* skipping mutations detected by CGP (MoST 17)

INDICATION:
Pathologically confirmed metastatic non-squamous NSCLC harbouring *METex14* skipping mutations detected by CGP in the ASPiRATION study

INTERVENTION:
Tepotinib 500 mg daily until disease progression or unacceptable toxicity

STATUS:
In follow up

Trial status correct as at 6 March 2025

Trial status correct as at 6 March 2025

CLINICAL TRIALS

TITLE: CHEST-RT
Chemotherapy and Immunotherapy in extensive stage small cell lung cancer with thoracic radiotherapy

COLLABORATION WITH:
Trans Tasman Radiation Oncology Group (TROG) Trial 20.01

CLINICAL TRIAL DESIGN:
Single arm open label prospective multicentre Phase II clinical trial

INDICATION:
ES-SCLC

INTERVENTION:
Thoracic radiation therapy in combination with immunotherapy (durvalumab) and chemotherapy (cisplatin/carboplatin and etoposide)

SUMMARY:
CHEST RT is investigating the safety and effectiveness of combining chemotherapy and immunotherapy with chest radiation therapy for the treatment of ES-SCLC. For over 20 years, a combination of chemotherapy using etoposide with either cisplatin or carboplatin has been used to treat ES-SCLC. Adding immunotherapy to the chemotherapy combination has been shown to help boosts the body's natural defences to fight cancer, improving response to treatment. This combination of chemotherapy with immunotherapy is now the standard of care treatment.

Research has shown that radiation therapy also improves the ability of the immune system to recognise tumours. The researchers would like to investigate whether combining radiation therapy with the standard chemo/immunotherapy may further improve patients' response to treatment.

RECRUITMENT TARGET:
35

STATUS:
In follow up

TITLE: BR.31
A Phase III Prospective Double Blind Placebo Controlled Randomized Study on the effect of Adjuvant MEDI4736 on Disease Free Survival In patients with Completely Resected NSCLC

COLLABORATION WITH:
Canadian Cancer Trials Group (CCTG)

CLINICAL TRIAL DESIGN:
Randomised, placebo-controlled double blind Phase III clinical trial

INDICATION:
Stage IB-IIIA resected primary NSCLC

INTERVENTION:
20mg/kg MEDI4736 (durvalumab) by intravenous infusion every 4 weeks for a maximum of 12 months following surgical resection

SUMMARY:
The purpose of this clinical trial is to find out whether it is better to receive the new drug, MEDI4736, or no further treatment after surgery (and possibly chemotherapy) for early-stage NSCLC. This is known as adjuvant immunotherapy (or chemoimmunotherapy) treatment. The study involves randomly allocating participants to receive treatment with either MEDI4736 or placebo. Participants will be required to receive intravenous infusions of MEDI4736 or placebo (2:1 randomisation) at 20mg/kg every 4 weeks for 12 months. Participants will then be followed up for a maximum of 10 years to assess overall survival and disease-free survival.

FINAL RECRUITMENT NUMBER:
114

STATUS:
In follow up

Trial status correct as at 6 March 2025

TITLE: ZENERGISE
Cancer survivors experiencing Cancer-Related Fatigue (CRF). A study evaluating a combined Physical Activity (PA) and Mindfulness program (The ZENERGISE trial)

CLINICAL TRIAL DESIGN:
Step 1 is a pilot study testing feasibility of combined intervention to review outcomes and inform protocol accordingly. Step 2 is a randomised Phase 2 non-comparative / parallel 2-arm trial of the combined physical activity (PA) and mindfulness-based stress reduction (MBSR) intervention, and PA alone.

INDICATION:
Patients who have initial CRF score ≥4/10 (moderate to severe fatigue) and who will have completed primary adjuvant cancer treatment within the previous 6–60 months, with no evidence of recurrence.

INTERVENTION:
Combined online MBSR and PA intervention taking 3 hours per week.

SUMMARY:
Cancer Related Fatigue (CRF) is one of the most prevalent, persistent and distressing patient-reported symptoms associated with cancer and its treatment. Physical activity (PA) and psychosocial interventions targeted specifically for CRF have independently been shown to reduce CRF, with more robust evidence supporting PA. Mindfulness Based Stress Reduction (MBSR) is an emerging strategy to address a number of conditions, such as depression and Chronic Fatigue Syndrome.

The aim of this study is to determine if a combined PA and MBSR intervention is active in improving CRF in cancer survivors.

RECRUITMENT TARGET:
65

STATUS:
Completed. Publication in progress

TITLE: PEARL
Efficacy of early referral to palliative care for improving quality of life and health care resources following recent diagnosis of advanced thoracic malignancies

CLINICAL TRIAL DESIGN:
Phase III randomised, controlled clinical trial

INDICATION:
Adults with advanced thoracic malignancy (NSCLC, SCLC or malignant pleural mesothelioma) that have been newly diagnosed within the last 60 days.

INTERVENTION:
Early referral to a hospital-based palliative care service for the specified palliative care intervention while receiving standard oncological care.

RESULTS:
The trial showed that the group who were referred early to palliative care had similar outcomes to those referred later at the discretion of their treating oncologist. Symptoms, quality of life, and survival time were similar in the two groups of participants. The carers of participants in the two groups also had similar satisfaction with care and quality of life. The conclusion of the PEARL investigators was that the palliative care needs of people with advanced lung cancer, and their carers, were equally well addressed, regardless of whether they were referred early, or at the discretion of their treating oncologist.

FINAL RECRUITMENT NUMBER:
113

STATUS:
Completed. Publication in progress

Trial status correct as at 6 March 2025

CLINICAL TRIALS

TITLE: OUTRUN

Randomised phase II trial of Osimertinib with or without stereotactic radiosurgery for EGFR mutated NSCLC with brain metastases

COLLABORATION WITH:

Trans Tasman Radiation Oncology Group (TROG) Trial 17.02

CLINICAL TRIAL DESIGN:

Phase II randomised, controlled, open label clinical trial

INDICATION:

EGFR-mutation positive NSCLC patients with brain metastases

INTERVENTION:

Stereotactic Radiosurgery (SRS) followed by 80mg Osimertinib taken once daily

SUMMARY:

Twenty to forty percent of patients with NSCLC will develop brain metastases at some point during their disease. Osimertinib has demonstrated intracranial activity in EFGR-mutated NSCLC with leptomeningeal disease. Stereotactic radiosurgery (SRS) is a standard local treatment for patients with limited number of brain metastases. Currently, it is unclear whether adding SRS to osimertinib will result in superior intracranial disease control in patients with EGFR-mutated NSCLC with brain metastases diagnosed *de novo* or developed while on first line EGFR tyrosine kinase inhibitors (TKIs) such as erlotinib and gefinitib. The aim of this clinical trial is to compare the effects of osimertinib alone versus osimertinib plus SRS on intra-cranial disease control in EGFR-mutated NSCLC with brain metastases diagnosed or developed while on first line EGFR TKIs.

RECRUITMENT TARGET:

100

STATUS:

Manuscript in preparation

TITLE: ALKTERNATE

A single arm multi-centre translational proof of concept study investigating the safety and efficacy of alternating lorlatinib with crizotinib in a pre-treated advanced ALK-rearranged NSCLC population with disease progression on a 2nd generation ALK tyrosine kinase inhibitor (TKI)

CLINICAL TRIAL DESIGN:

Open-label Phase II single arm clinical trial

INDICATION:

ALK-rearranged advanced NSCLC with any number of lines of prior therapy with the immediately prior treatment a second generation ALK inhibitor

INTERVENTION:

All participants enrolled in this clinical trial began with Induction therapy which involved taking lorlatinib tablets every day for 12 weeks. Participants then moved onto the Alternating phase and took crizotinib for 4 weeks, then lorlatinib for 8 weeks, then crizotinib for another 4 weeks, and lorlatinib for 8 weeks until disease progression or unacceptable side effects.

SUMMARY:

The primary purpose of this clinical trial was to evaluate the efficacy, safety and feasibility of alternating lorlatinib and crizotinib for the treatment of ALK-rearranged advanced NSCLC, and to provide information on the potential to delay the emergence of drug resistance as compared to continuous lorlatinib therapy alone. The study found that alternating crizotinib and lorlatinib could be done safely and did not compromise the control of cancer compared to usual care. However, since the trial commenced, lorlatinib has become first line standard of care therapy for ALK+ NSCLC. Blood samples collected from patients during treatment on the ALKTERNATE clinical trial revealed that every ALK+ NSCLC patient is different, with no one clear mechanism identified for resistance to treatment.

RECRUITMENT TARGET:

25 (Closed with 15 participants only due to poor recruitment)

STATUS:

Published

Trial status correct as at 6 March 2025

TITLE: OSCILLATE

Phase 2 trial of alternating osimertinib with gefitinib in patients with EGFR-T790M mutation positive advanced NSCLC

CLINICAL TRIAL DESIGN:

Single arm Phase II clinical trial

INDICATION:

EGFR-T790M mutation positive advanced NSCLC patients who have received prior therapy with an EGFR-TKI

INTERVENTION:

All participants began induction therapy with Induction therapy of 80mg Osimertinib daily for 8 weeks. Participants then moved onto the 'Oscillating' phase of 250mg gefitinib daily for 4 weeks, then 80mg Osimertinib for 4 weeks, and continue alternating 4 weekly cycles of each drug until disease progression or unacceptable toxicity. At clinician discretion, alternating or continuous osimertinib may have been continued after progression.

RESULTS:

Sixty-eight percent of participants completed the alternating therapy without any dose interruptions for six months, with a median duration of 9.4 months on alternating therapy. The safety profile of the alternating regimen was comparable to using either drug alone. While the OSCILLATE trial demonstrated that alternating therapy was safe and well tolerated, it provided similar clinical benefit to continuous osimertinib, with a 12-month progression-free survival rate of 38% and a median overall survival of 26 months.

Serial insulating tumour DNA analysis allowed real-time tracking of tumour evolution and resistance mechanisms, revealing that while certain known 'escape populations were successfully suppressed, alternative resistance pathways emerged.

FINAL RECRUITMENT NUMBER:

49 (47 included, 2 excluded)

STATUS:

Published

TITLE: STIMULI

Phase II trial to assess the overall survival benefit for patients with the use of nivolumab and ipilimumab in limited-stage SCLC after chemo-radiotherapy

CLINICAL TRIAL DESIGN:

Randomised open-label Phase II clinical trial

INDICATION:

Untreated limited-stage SCLC

INTERVENTION:

During the induction phase patients received nivolumab at a dose of 1 mg/kg intravenously followed by ipilimumab at a dose of 3 mg/kg intravenously once every 3 weeks for 4 cycles. During the following maintenance phase patients received nivolumab 240 mg intravenously once every 2 weeks for a maximum of 12 months (no minimum time for the maintenance phase). All patients received standard care of chemo-radiotherapy.

RESULTS:

The results of the STIMULI trial showed no significant difference between the ipilimumab and nivolumab (immunotherapy) and observation groups. Overall, there was no difference in the percentage of people with cancer progression at 12 and 24 months after starting immunotherapy or observation. There was also no difference in the percentage of people alive at 24 months, and the amount of tumour shrinkage was no different between the two groups. There was some data to suggest that immunotherapy after a more frequent radiotherapy schedule may be more effective, but this needs to be studied further.

FINAL RECRUITMENT NUMBER:

6

STATUS:

Published

Trial status correct as at 6 March 2025

CLINICAL TRIALS

TITLE: NIVORAD

A randomised phase 2 trial of nivolumab and stereotactic ablative body radiotherapy (SABR) in advanced NSCLC, progressing after 1st or 2nd line chemotherapy

CLINICAL TRIAL DESIGN:

Randomised, controlled open-label clinical trial

INDICATION:

Advanced NSCLC, progressing after first of second line chemotherapy.

INTERVENTION:

A single fraction of SABR between days 8-14 of nivolumab cycle 1. All patients will receive Nivolumab (immunotherapy) 240mg (iv infusion) every 2 weeks

RESULTS:

The results of NIVORAD showed that nivolumab seemed to work equally well with SABR or without SABR to a single spot of cancer. The proportions of participants with tumours that were controlled for at least 6 months, and with tumours that shrank substantially were about the same in both groups. The side effects of treatment were also about the same in the two groups.

FINAL RECRUITMENT NUMBER:

50

STATUS:

Published

TITLE: BR.34

A randomised trial of Durvalumab and Tremelimumab +/- Platinum-Based Chemotherapy in Patients With Metastatic (Stage IV) Squamous or Non-Squamous NSCLC

CLINICAL TRIAL DESIGN:

Randomised, controlled open-label clinical trial

INDICATION:

Advanced NSCLC, progressing after first of second line chemotherapy

INTERVENTION:

Nivolumab 240mg (iv infusion) every 2 weeks plus a single fraction of SABR between days 8-14 of nivolumab cycle 1) Stereotactic Ablative Body Radiotherapy (SABR)

SUMMARY:

BR.34 compared the overall survival following an immunotherapy treatment combination of both durvalumab plus tremelimumab with or without chemotherapy in metastatic NSCLC. Participants were allocated by chance to one of two treatment groups. Participants in both groups received durvalumab and tremelimumab every 28 days for 4 cycles followed by durvalumab every 28 days until disease progression. Participants in one group only also received one of two types of chemotherapy during durvalumab and tremelimumab treatment. Patients with squamous cell NSCLC received gemcitabine and cisplatin or carboplatin chemotherapy, and patients with non-squamous NSCLC received pemetrexed and cisplatin or carboplatin chemotherapy.

FINAL RECRUITMENT NUMBER:

53

STATUS:

Published

Trial status correct as at 6 March 2025

TITLE: ILLUMINATE

A Phase 2 trial of durvalumab (MEDI4736) and tremelimumab with chemotherapy in metastatic EGFR+ non-squamous NSCLC following progression on EGFR TKIs

CLINICAL TRIAL DESIGN:

Open-label Phase II clinical trial with two treatment cohorts (T790M+ve & T790M-ve)

INDICATION:

Relapsed NSCLC with EGFR mutation of Exon 19 deletion or Exon 21 L858R point mutation and either (i) no evidence of T790M or (ii) T790M and progression on a 3rd generation TKI.

INTERVENTION:

Four 3 weekly cycles of induction chemotherapy and immunotherapy (durvalumab and tremelimumab), followed by 4 weekly maintenance therapy of pemetrexed and durvalumab.

SUMMARY:

Third generation TKIs were designed to be active against the T790 mutation, which often led to resistance to therapy with earlier generation TKIs in EGFR+ metastatic NSCLC. However, some patients still progressed on third generation EGFR TKIs, or progressed on other EGFR TKI therapy with no evidence of the T790 mutation. At the time the ILLUMINATE study commenced, the role of immunotherapy for this subset of patients was unclear. Various studies suggested benefit, but differed in whether immunotherapy was delivered as monotherapy, as a dual immunotherapy combination or together with chemotherapy. The primary purpose of this clinical trial was to evaluate the efficacy and tolerability of immunotherapy (durvalumab and tremelimumab) with platinum-pemetrexed chemotherapy in patients with metastatic EGFR-mutant NSCLC (T790M+ve or T790M-ve) who had progressed following prior EGFR TKI therapy.

RECRUITMENT TARGET:

229

STATUS:

Published

TITLE: DREAM

A phase 2 trial of durvalumab with first line chemotherapy in mesothelioma

CLINICAL TRIAL DESIGN:

Open-label Phase II clinical trial with two treatment cohorts (T790M+ve & T790M-ve)

INDICATION:

Chemotherapy-naïve patients with malignant pleural mesothelioma (MPM) of all histological subtypes.

INTERVENTION:

Durvalumab, cisplatin and pemetrexed 3-weekly for a maximum of 6 cycles, followed by durvalumab alone until progression or to 12 months total therapy.

RESULTS:

The trial shows that the combination of durvalumab and standard chemotherapy was safe and has promising effects against mesothelioma. Tumour imaging by CT showed that 31 of 54 patients (57%) were alive and progression free at 6 months, which was higher than the expected outcomes with chemotherapy alone. The combination of durvalumab, cisplatin and pemetrexed showed promising activity and an accepted safety profile.

RECRUITMENT TARGET:

55 (1 patient ineligible)

STATUS:

Published

Trial status correct as at 6 March 2025

FINANCIAL STATEMENT

STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the Year Ended 30 June 2024

	2024	2023
	$	$
Revenue	**1,867,819**	1,709,798
Events expenses	**(266,377)**	(302,731)
Sponsorship expenses	**(3,500)**	(1,244)
Advertising expenses	**(43,025)**	(11,302)
Administrative expenses	**(177,026)**	(116,667)
Employee benefits expense	**(399,211)**	(307,899)
Other expenses	**(6,175)**	(8,783)
Surplus for the year	**972,505**	961,172
Other comprehensive income	**-**	-
Surplus for the year	**972,505**	961,172

STATEMENT OF FINANCIAL POSITION

As at 30 June 2024

	2024	2023
	$	$
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	**4,189,452**	3,303,159
Trade and other receivables	**149,618**	106,628
Other assets	**152,279**	-
TOTAL CURRENT ASSETS	**4,491,349**	3,409,787
TOTAL ASSETS	**4,491,349**	3,409,787
LIABILITIES		
CURRENT LIABILITIES		
Trade and other payables	**61,490**	77,357
Employee benefits	**30,728**	20,944
Deferred revenue	**594,989**	479,849
TOTAL CURRENT LIABILITIES	**687,207**	578,150
TOTAL LIABILITIES	**687,207**	578,150
NET ASSETS	**3,804,142**	2,831,637
EQUITY		
Retained surplus	**3,804,142**	2,831,637
TOTAL EQUITY	**3,804,142**	2,831,637

FINANCIAL STATEMENT

STATEMENT OF CHANGES IN EQUITY

For the Year Ended 30 June 2024

2024

	Retained Surplus	Total
	$	**$**
Balance at 1 July 2023	**2,831,637**	**2,831,637**
Surplus for the year	**972,505**	**972,505**
Balance at 30 June 2024	**3,804,142**	**3,804,142**

2023

	Retained Earnings	Total
	$	**$**
Balance at 1 July 2022	1,870,465	1,870,465
Surplus for the year	961,172	961,172
Balance at 30 June 2023	2,831,637	2,831,637

SUPPORTERS & PARTNERS

Recognition for our Invaluable Supporters and Partners.

SIGNIFICANT GIFTS OR FUNDRAISING OVER $2,000.

TOGA is grateful to have received major contributions from a number of individuals and organisations since its establishment in 2020. Much of TOGA's work has been made possible through the help of our generous supporters who have fundraised or donated to our cause. Their significant gifts allow us to take great leaps forward in the lung cancer cures. We are truly thankful for this support.

Our thanks go to (both those listed below, and those who have chosen to remain anonymous):

- ADFA
- Alison Bolton
- Ben Solomon
- Claire Monk
- Dale Massie
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- Elise Dunstan
- Graham Monk
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- Lynne and Simon Thornton
- Malinda Itchins
- Megan Sanders
- Melissa Moore
- Michael and Natalie Dubs
- Nick Pavlakis
- Olivia Mandalinic (Slater & Gordon Lawyers)
- Ping Onn Mak
- Rachel Wong
- Raelene Lingam (Slater & Gordon Lawyers)
- Turner Freeman Lawyers

Thank you for believing in the work we do, you make a difference in the lives of people affected by lung cancer every day. With you unwavering support, we have every reason to be filled with optimism for our ultimate vision of a world free from thoracic cancers (lung cancer) as a cause of death, disability and suffering.

SPONSORS

We thank our sponsors who have supported TOGA this year. Your contribution is vital to continue our important work and has made a tremendous impact on our cause. We are extremely thankful for your generous sponsorship.

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HOW YOU CAN SUPPORT US

GIVE:

Your donation can help support research to extend quality of life and survival for the 36 Australians diagnosed with lung cancer each day.

LEAVE A GIFT IN WILL:

After taking care of your loved ones, leaving a Gift in Will is a valuable way of supporting the continuation of high-quality research into thoracic cancers.

FUNDRAISE:

Get involved in one of our fundraising events, or create your own.

BECOME A MEMBER:

You can join TOGA as a community, industry, medical doctor or other clinical professional and contribute to the design and development of high-quality research.

PARTNER WITH US:

There are many ways your organisation can make an impact and be part of changing the poor outcomes from thoracic cancers.

TOGA

Thoracic Oncology Group Australasia

P.O. Box 1103
Thornbury, VIC 3071
ABN: 47 641 984 198

Phone: +61 (0)3 9087 3550
Email: info@thoraciconcology.org.au
www.thoraciconcology.org.au