

Melanoma and Skin Cancer Trials

Limited

ANNUAL REPORT 2022-23



CONQUERING MELANOMA AND SKIN CANCER

Melanoma and Skin Cancer Trials

*Formerly Australia and New Zealand
Melanoma Trials Group*

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@AOMA_MASC



@AMIGOs_MASC



@MASCTrials

Melanoma and Skin Cancer Trials acknowledges and pay respect to the Traditional Custodians of the lands across Australia on which our members live and work, and to their Elders, past, present, and future. We pay respect to the Wurundjeri Peoples as the Traditional Custodians of the land on which our office stands. Melanoma and Skin Cancer Trials acknowledges Māori as tangata whenua and Treaty of Waitangi partners in Aotearoa New Zealand.

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About us

Australia has the highest incidence of melanoma in the world.

Two in every three Australians will be diagnosed with skin cancer by the age of 70.

Conquering melanoma and skin cancer

Melanoma and Skin Cancer Trials works with world-leading researchers to deliver clinical trials that improve melanoma and skin cancer outcomes. We are the only independent, not-for-profit, multi-site, collaborative clinical trials group focused on melanoma and skin cancer in Australia and New Zealand.

Our clinical trials portfolio covers the prevention, early detection and treatment of melanoma and skin cancer, including early to late phase clinical trials. Importantly, we also investigate rare forms of skin cancer such as Merkel cell carcinoma and melanoma of the eye.

We believe all Australians and New Zealanders should be able to access clinical trials, which is why we continue to work with our networks to open more trial sites in regional Australia and in New Zealand.

International network boosts research

Our 2,396 members throughout Australia and around the world represent the many disciplines critical to our work and strengthen the success of our clinical trials. Together, we work to reduce the burden of melanoma and skin cancer.

From early engagement with consumers and researchers to develop research concepts, through to the publication of results, we work cooperatively to provide a range of clinical trial services. We value the lived experiences of consumers, and our collaborative approach ensures their unique perspectives are considered in clinical trial prioritisation, development, and implementation.

Our endorsement of clinical trial and research concepts provides them with a badge of quality, increases their chance of being funded, and has been a key factor in our success.

Supported by leading institutions and generous donors

Melanoma and Skin Cancer Trials continues to be supported by the Australian Government via Cancer Australia, Monash University, and the generosity of our industry partners and donors.

Our academic affiliation with Monash University and its Melanoma and Skin Cancer Research Centre within the School of Public Health and Preventive Medicine, enhances our research activities. As one of Australia's top universities, Monash University provides access to state-of-the-art facilities, leading academics, and excellent support services.

Our services

We assist researchers across all facets and stages of clinical trials, including:

- Research concept development and endorsement
- Support for grant preparation and submission
- Biostatistics and health economics modelling
- Quality of life and patient reported outcome modelling
- Facilitating active partnerships with consumer advocates and patients
- Mentoring and peer review opportunities for researchers via Discipline-Specific Advisories
- Trial budget development and management
- Trial design and protocol development
- Ethics submission and protocol compliance
- Feasibility evaluation and site selection
- Access to local and international trial recruitment networks
- Site initiation training and trial start-up
- Trial and research project management
- Data and safety monitoring
- Database build and data management
- Monitoring and data validation
- Close-out and archive

The high-quality evidence published from our clinical trials improves melanoma and skin cancer outcomes.

Vision, mission & values

Vision

Eliminate melanoma and skin cancer

Mission

We work collaboratively with world-leading researchers to deliver clinical trials that improve melanoma and skin cancer outcomes

Values

**Collaboration
Compassion
Innovation
Impact**

Conquering melanoma and skin cancer through clinical trials

Our history

1999

Australia and New Zealand Melanoma Trials Group (ANZMTG) founded

2000

First ANZMTG trial developed with TROG

2002

ANZMTG Executive Committee formed, based at Royal Prince Alfred Hospital in Sydney

2008

Cancer Australia core funding secured via University of Sydney
First Annual Scientific Meeting

2009

First national clinical trial grant secured

2010

ANZMTG transitions with MIA to the Poche Centre, Sydney

2011

First international partnership
500 members reached

2014

First project management of a medical oncology clinical trial

2015

Recipient of National Excellence Award

2016

1,000 members

2017

First NHMRC clinical trial grant secured
Formation of the Australasian Merkel Cell Carcinoma Interest Group (AMIGOs) and the Australasian Ocular Melanoma Alliance (AOMA)

2018

Discipline-Specific Advisories (DSA) launched
First MRFF clinical trial grant secured
ANZMTG incorporates as Melanoma and Skin Cancer Trials Limited (MASC Trials)

2019

Research agreement formed with Monash University
MASC Trials transitions to Monash University, based in Melbourne
First AOMA Summit

2020

New MASC Trials website launched
1,957 members

2021

Virtual Annual Scientific Meeting
2,148 members
Skin Cancer DSA formed
Consumer Advisory Panel formed

2022

Foundation Club 100 launched
BETTER trial initial funding
SOCRATES trial opens
SMARTI trial results published

2023

2,396 members
Annual Scientific Meeting alongside Australasian Melanoma Conference
First Concept Development Workshop
CHARLI trial results presented at ASCO

2022/23 snapshot



1263

**Participants Recruited
in Trials**



5

Recruiting Trials



2

Trials in Start-Up



8

**Active Trials Closed
for Recruitment**



43

**Australian Trial Sites
Actively Recruiting**



248

New Members



11

Participating Countries



2396

Total Members



35

**Countries with
Members**



13

**Melanoma and Skin
Cancer Trials Staff**



1000+

Investigators Worldwide



18

**Publications and
Conference Presentations**



4

Scientific Events

2022-23 trial summary

Trials in start-up

Skin cancer

SiroSkin

*Estimated first participant recruited:
December 2023*

Melanoma

BETTER

*Estimated first participant recruited:
February 2024*

Recruiting trials

Melanoma

MelMarT-II

Sites: 138
Participants: 1,354

SOCRATES

Sites: 3
Participants: 3

Merkel cell carcinoma

GoTHAM

Sites: 6
Participants: 15

I-MAT

Sites: 19
Participants: 79

Uveal melanoma

Uveal Melanoma Registry

Sites: 8
Participants: 101

Active trials closed for recruitment

Melanoma

IMAGE

Sites: 12
Participants: 670
Closed recruitment: April 2023

CHARLI

Sites: 10
Participants: 52
Closed recruitment: December 2021

EAGLE FM

Sites: 15
Participants: 101
Closed recruitment: March 2020

RTN2

Sites: 23
Participants: 50
Closed recruitment: February 2020

WBRTMel

Sites: 39
Participants: 215
Closed recruitment: September 2017

MelMarT Pilot

Sites: 20
Participants: 400
Closed recruitment: August 2016

Lentigo maligna

RADICAL

Sites: 10
Participants: 126
Closed recruitment: December 2021

Completed trial and research study

Skin cancer

SMARTI

Sites: 2
Participants: 214
Publications:
- *Journal of the American Academy of Dermatology*
- *BMJ Open*

Improving melanoma and skin cancer awareness in regional and rural Australia

143 media items
138 social media posts
8 resources produced
10 educational videos

Year at a glance

Date	Events
July 2022	<ul style="list-style-type: none"> AOMA Virtual Summit held with 200 registrations
August 2022	<ul style="list-style-type: none"> Australian Skin Cancer Foundation donates \$100,000 to BETTER trial Foundation Club 100 launched
September 2022	<ul style="list-style-type: none"> MelMarT-II enrolls 850 participants across 66 sites worldwide
October 2022	<ul style="list-style-type: none"> SMARTI trial results published in <i>Journal of the American Academy of Dermatology</i>
November 2022	<ul style="list-style-type: none"> GoTHAM reaches 30% recruitment target Uveal Melanoma Registry opens additional sites in South Australia
December 2022	<ul style="list-style-type: none"> SOCRATES trial opens first site at Monash Medical Centre 1st Christmas fundraising appeal launched Regional education campaign with Melanoma and Skin Cancer Advocacy Network and BlazeAid
January 2023	<ul style="list-style-type: none"> MelMarT-II trial enrolls 1,000th participant Mackay Hospital, a regional teletrial site, enrolls its 1st participant in I-MAT trial
February 2023	<ul style="list-style-type: none"> Australian Skin Cancer Foundation donates \$110,000 to BETTER trial SOCRATES trial opens at Cabrini Hospital
March 2023	<ul style="list-style-type: none"> Annual Scientific Meeting held as satellite meeting of the Australasian Melanoma Conference, Brisbane IMAGE trial protocol paper published in <i>Trials Journal BioMed Central</i> RTN2 and EAGLE FM trial results presented at Australasian Melanoma Conference MelMarT-II Investigator Meeting held at International Conference on Surgical Cancer Care, Boston, USA
April 2023	<ul style="list-style-type: none"> Katja Loewe promoted to Research Manager IMAGE trial reaches recruitment target SiroSkin trial receives ethics approval SOCRATES trial enrolls 1st participant
May 2023	<ul style="list-style-type: none"> 1st tax-time fundraising appeal launched
June 2023	<ul style="list-style-type: none"> CHARLI trial results poster presented at American Society of Clinical Oncology meeting, Chicago, USA 1st Concept Development Workshop AOMA Virtual Summit broadcast to 19 countries I-MAT reaches 60% recruitment target



Message from our Chair



Over the past decade, the rapid medical advances in melanoma and skin cancer have been truly astounding. Before the introduction of immunotherapy and targeted therapies for melanoma, this disease was often a death sentence. Now, patients with the most severe form of metastatic melanoma have a good chance of living long and productive lives.

Clinical trials continue to play a pivotal role in bringing innovative and incredibly effective treatments into standard medical practice and refining the use of existing treatments to improve patient outcomes. Australia has been at the forefront of this clinical research, and I'm incredibly proud of the contribution Melanoma and Skin Cancer Trials has made to this effort.

Our collaborative clinical trials group began in 1999, before our new therapies were discovered and when outcomes for melanoma and skin cancer patients were poor. In our early days, we were a small group of investigators with little funding and support, but great determination. Through hard work and the talent of investigators we have worked with along the way, we are now a national organisation that has delivered 29 clinical trials with over 7,000 participants. We are backed by Cancer Australia, industry, and leading research organisations, and have an academic affiliation with Monash University.

Working with investigators worldwide has enhanced our international presence. In particular, the Melanoma Margins Trial, MelMarT-II, has allowed us to collaborate with world-leading experts in melanoma excision at 138 sites across eight countries. Through one of our priority special interest groups, the Australasian Ocular Melanoma Alliance (AOMA), we have attracted interest in AOMA's work from 19 countries.

Back home, we believe all Australians should be able to access clinical trials no matter where they live. That's why we now have 14 regional trial sites and continue to open more so that Australians living outside of major cities can access our clinical trials. This year we included 204 participants from regional centres in our trials.

“Our vision is to eliminate melanoma and skin cancer.”

Prof Mark Shackleton
Chair, Melanoma and Skin Cancer Trials

With the return of face-to-face meetings, our Annual Scientific Meeting on 23 March 2023 in Brisbane was a sold-out success. Held for the first time as a satellite meeting of the Australasian Melanoma Conference, the meeting featured two international keynote speakers and 15 Australian speakers. The networking event afterwards allowed those attending to build valuable connections and catch up with colleagues from interstate.

I would like to acknowledge Paul White, who retired from the Melanoma and Skin Cancer Trials Board of Directors at the end of June 2023. Paul also retired as Deputy Chair of our Consumer Advisory Panel. Paul joined the Board in 2014, bringing expertise in financial and risk management in addition to his lived experience with melanoma. Paul was our Company Secretary from 2018 - 2023 and is one of our longest serving Board members. We thank Paul for his tremendous efforts over the years and for providing a consumer voice in the many decisions that have shaped Melanoma and Skin Cancer Trials into the national organisation it is today.

This year we began a concerted effort to attract philanthropic donations to support our clinical trials. One of our first fundraising initiatives was Foundation Club 100, which is open to our first 100 major donors. I sincerely thank all the generous individuals who joined Foundation Club 100 this year and I look forward to welcoming many more members next year. To learn more, visit masc.org.au/support

A handwritten signature in black ink, appearing to read 'Mark Shackleton'.

Professor Mark Shackleton MBBS PhD FRACP
Chair, Melanoma and Skin Cancer Trials
Director of Oncology, Alfred Health
Professor of Oncology, Monash University
Co-Director, Monash Partners Comprehensive Cancer Consortium

Message from our CEO



“I am particularly proud of our focus on two rare cancers: uveal melanoma and Merkel cell carcinoma.”

Gabrielle Byars
CEO, Melanoma and Skin Cancer Trials

With an unwavering commitment to advancing melanoma and skin cancer clinical trials, this year we have grown our clinical trial portfolio to include 15 clinical trials in various stages, from start-up through to longer term follow-up.

Patient recruitment increased more than ever before with 1,263 new participants enrolled across 11 countries. These achievements are testament to the excellent work of our investigators and their teams throughout the world.

Our network of health professionals and researchers specialising in melanoma and skin cancer continues to increase. We are also attracting more melanoma and skin cancer consumers interested in our work and aligning with our outreach efforts. This year, our membership grew to 2,396 across 35 countries.

While these impressive numbers demonstrate our overall success, I am particularly proud of our focus on two rare forms of skin cancer, uveal melanoma, a rare type of eye cancer, and Merkel cell carcinoma. Compared to melanoma, which is Australia's third most diagnosed cancer, these rare and aggressive cancers are only diagnosed in a few hundred Australians each year. Yet both cancers have a very poor prognosis and treatment options are limited. Collecting real world data within our Uveal Melanoma Registry is key to documenting clinical management globally and informing best-practice. Our Merkel cell carcinoma trials – GoTHAM and I-MAT – aim to deliver better treatment options that improve the overall outcomes for these patients.

This year we supported Prof Stephen Nicholls and the Monash Victorian Heart Institute to open the SOCRATES trial. SOCRATES is a unique collaboration between medical specialties from oncology, dermatology, and cardiology to determine if a common cholesterol-lowering drug can prevent heart disease in melanoma patients who are being treated with immunotherapy. We are also providing data management support for the Australian Centre of Excellence in Melanoma Imaging and Diagnosis (ACEMID) Cohort Study, led by Prof H. Peter Soyer, University of Queensland.

We will soon launch our SiroSkin trial with Prof Kiarash Khosrotehrani from the University of Queensland. This trial will investigate whether a topical cream can reduce the number of facial tumours in organ transplant recipients, who are at greater risk of developing skin cancer. If successful, this treatment will reduce the burden of skin cancers on these patients.

It has been a delight to work with the Australian Skin Cancer Foundation this year, who have generously donated \$210,000 to kickstart the BETTER trial, which is investigating a new treatment combination for melanoma that has spread to the brain. Melanoma brain metastases occur in more than a third of patients with an advanced melanoma diagnosis. These patients often have a poor prognosis and a short life expectancy, so improved treatment options are urgently needed.

During the year we consolidated our team. I welcome the following staff to their new roles and to the team.

- Katja Loewe, Research Manager (formerly Senior Clinical Research Associate)
- Dr Sam Hogarth, Research Development Officer / Clinical Research Associate
- Carla Duarte, Clinical Research Associate
- Ally McGill, Finance and Administration Officer

Our group has a solid reputation for delivering impactful clinical trials that improve melanoma and skin cancer outcomes. However, we need additional support to expand our melanoma and skin cancer clinical trials and make an even greater impact on the lives of those affected by these cancers. Your support will help us to conquer melanoma and skin cancer.

Visit masc.org.au/donate

A handwritten signature in black ink, appearing to read 'G Byars'.

Gabrielle Byars BSc MBioMedSci
Chief Executive Officer, Melanoma and Skin Cancer Trials

Melanoma patient joins clinical trial to help others

As an avid collector of Six Million Dollar Man memorabilia, Stuart Chynoweth is no stranger to the idea of life improving after surgery. But since being diagnosed with melanoma in late 2022, Stuart has undergone a series of operations to rival the iconic Steve Austin.

Stuart's melanoma journey began when he knocked a mole on the back of his knee and it bled. A biopsy confirmed it was a melanoma and a couple of weeks later he underwent surgery to remove the mole at the Royal Adelaide Hospital.

Stuart said he was shocked with the diagnosis but did his best to take it in his stride. "Melanoma certainly was not on my radar, so it came as a nasty surprise. My partner had been diagnosed with breast cancer, so after that emotional time I knew I just needed to get on with it, listen to the experts, and get the best treatment possible."

Getting the best care while also contributing to research

Luckily for Stuart, the Royal Adelaide Hospital was a site for the Melanoma Margins Trial, MelMarT-II, which is investigating the optimal excision margin for stage II melanoma. Stuart didn't hesitate to sign up for the clinical trial.

"I jumped at the chance to take part in the trial. Here was an opportunity to not only get the best care but to also do my little bit to help others. Melanoma isn't going away, so if I can contribute to this important research and improve treatment options for people diagnosed in the future, then that's the least I can do."

Melanoma surgery is a delicate balance

Patients like Stuart who have stage II primary cutaneous melanoma – where the cancer cells have penetrated deeply into the skin but haven't spread to other parts of the body – undergo surgery to remove the melanoma completely. For high-risk melanoma patients, their doctor's decision to use either a 1 cm or 2 cm excision margin around the melanoma could impact their quality of life and survival.

A larger excision margin can lead to complex surgical reconstruction, poorer cosmetic appearance, post-operative complications, and impact on function. On the other hand, if the excision margin is too small, the melanoma might return or spread.

Clinical trial to find the answer and save lives

Currently there is no high-quality clinical trial evidence or consensus in the medical community about the optimal melanoma excision margin size for stage II melanoma. The evidence available suggests a 1 cm margin is reasonable. The MelMarT-II trial will determine whether a 1 cm or a 2 cm margin is best and provide certainty for melanoma patients and their doctors in deciding the most effective treatment.

Led by Australian investigators and Melanoma and Skin Cancer Trials, the MelMarT-II trial will study almost 3,000 patients across eight countries, including major coordinating trial centres in Australia, Europe, and North America. The results of this global effort will help determine the best surgical treatment for stage II melanoma, leading to better outcomes for melanoma patients in Australia and around the world.

"I jumped at the chance to take part in the trial."

Stuart Chynoweth, MelMarT-II trial participant



Board of Directors

Expert guidance

Melanoma and Skin Cancer Trials is governed by a volunteer Board of Directors, comprising experts in melanoma and skin cancer from leading health and research institutions in Australia and New Zealand. The Board also includes members from government and the business community, and consumers with a lived experience of skin cancer. The Board is chaired by Prof Mark Shackleton, who holds leadership positions across numerous cancer-focused organisations including Alfred Health and Monash University.

Yearly update

The Board of Directors met six times during the year. They also conducted two strategic planning days to discuss the future directions of Melanoma and Skin Cancer Trials.



Prof Mark Shackleton
MBBS PhD FRACP
Chair, Medical Oncologist



Prof Andrew Spillane
MD FRACS BMBS BMedSci GAICD
Deputy Chair, Surgical Oncologist



Paul White
FCA FGIA CIA GAICD
Company Secretary, Patient Advocate



A/Prof Victoria Mar
MBBS PhD FACD
Dermatologist



Mr Richard Martin
MBChB FRACS ChMSurgOnc
Surgical Oncologist



Prof Michael Kimlin
BSc MSc GradDipEd PhD MAICD
Cancer Epidemiologist



Mary Tsouvalakis
BA LLBHons MPH
Lawyer, Patient Advocate



Sharon Van Buerle
BEc GradDipAppSci
Policy and Financial Resources
Management



Prof Sophia Zoungas
MBBS FRACP PhD
Endocrinologist

Our team (As of 30 June 2023)



Gabrielle Byars
BSc MBioMedSci
Chief Executive Officer



Katja Loewe
MSc
Research Manager



Merrin Morrison
BBusComm GradDipBusMgmt
Marketing and Communications
Manager



Dr Sam Hogarth
BBIotechMedRes PhD
Research Development Officer /
Clinical Research Associate



Sharon Jones
BSc (Hons) MSc
Senior Clinical Research Associate



Louise Gonzales
BAppSc
Clinical Research Associate



Carla Duarte
BSc (Hons)
Clinical Research Associate



Simon Cumming
BSc GradDipComp
Clinical Data Manager



Daniel Ariza Ospino
BDS MPH
Clinical Data Manager



Lucas Skewis
BBioMedSci
Clinical Data Manager



Ally McGill
BSc CertIV Bookkeeping DipAcc
Finance and Administration Officer



Dr Alan Herschtal
PhD
Biostatistician (Monash University)



Prof Rory Wolfe
PhD
Biostatistician (Monash University)

Serendipity and dedication: an extraordinary career tackling cancer



As a young doctor, Prof Mark Shackleton – now one of Australia’s leading medical oncologists – was focused on becoming a neurologist. It was only later in his medical training that Prof Shackleton encountered a ward that profoundly changed everything and set him on a path to become an expert in melanoma and skin cancer, and a champion of clinical trials.

“One of my last rotations as a junior doctor just happened to be on an oncology ward. Outside of my studies, I’d never given much thought to that side of medicine, but the more I was exposed to people with cancer the clearer it became that oncology was where I was meant to be. The psycho-spiritual and existential aspects of cancer – people having to deal with profoundly challenging situations they’ve been thrust into through no fault of their own – really struck me. Those, as well as the exciting emerging advances in cancer research at the time, were more than enough to compel me – I knew I had to do all I could to improve patient outcomes.”

After that revelation, Prof Shackleton threw himself into medical oncology research, securing a subspecialist position that focused on novel treatments towards the end of his training. This was the 1990s: an exciting time for a young doctor at the cutting-edge, with treatments like targeted therapies, immunotherapy, and cancer vaccines showing early promise. And so, surrounded by mentors and other enthusiastic researchers, Prof Shackleton began to establish a reputation for himself.

“After my PhD at the Walter and Eliza Hall Institute, I took a postdoctoral research position specialising in melanoma at the University of Michigan in the USA. With amazing colleagues, I was lucky enough to drive some innovative research that generated positive results and media attention. We were making real progress and that was encouraging, particularly as I remembered the patients and their families I’d met on oncology wards, and the huge impact this research could have on them – and future generations of patients.”



Cancer research during this time was rapidly evolving. From the development of tablet-based therapies that targeted mutated BRAF proteins to the subclassification of various types of cancers, this era was punctuated by several watershed discoveries. And then came immunotherapy.

“For over 100 years, people had understood there was a link between the immune system and cancer, and that not all cancers and immune systems interact in the same way. Thanks to technological advancements and back-breaking research, and despite sometimes marginal funding, truly revolutionary breakthroughs were happening through the 80s, 90s and 2000s that led to what we now know as anti-cancer immunotherapy. As is the way with research, those learnings catalysed advancements that we’re still benefitting from.”

Now, as Board Chair of Melanoma and Skin Cancer Trials, and holding several senior leadership positions in the medical oncology world, Prof Shackleton can reflect on the significant advancements he has contributed to throughout his extraordinary career.

“I’ve been fortunate enough to be at the bleeding-edge of oncology research since the early stages of my career. It’s a real privilege to think some of the research we did in the immunotherapy space in the 1990s has led to where we are today.”

Prof Shackleton highlights that it’s not only medical staff who should receive the credit for improved patient care.

“From the trailblazers like dedicated laboratory researchers and past clinical trialists whose ground-breaking discoveries paved the way, through to the thousands of professionals working to deliver clinical trials, and the industry leaders and generous philanthropists who support our endeavours, their collective efforts continue to shape our progress. With so many promising developments being made, it’s truly an exciting time in history for melanoma and skin cancer clinical research.”



“With so many promising developments being made, it’s truly an exciting time in history for melanoma and skin cancer clinical research.”

Prof Mark Shackleton
Board Chair, Melanoma and Skin Cancer Trials

Consumer engagement

Improving trials through consumer input

The medical advances made through our clinical trials would not be possible without the thousands of melanoma and skin cancer patients who agree to take part in our research. To ensure our clinical trials are designed and conducted with the patient's best interests in mind, we regularly seek advice from our Consumer Advisory Panel.

Formed in 2021, our Consumer Advisory Panel helps our investigators to better understand the lived cancer experience and design trials with a patient-centred approach. They help researchers identify critical issues and barriers patients may face during a trial and co-develop patient friendly trial materials.

The guidance provided by our Consumer Advisory Panel ensures our investigators deliver clinical trials with impactful research outcomes that benefit patients and advance medical knowledge.

“The patient voice needs to be heard from the beginning of the research process. That’s why it’s important to have a collaborative and inclusive approach with consumers when developing clinical trials.”

Alison Button-Sloan
Chair, MASC Trials Consumer Advisory Panel

Yearly update

Led by Alison Button-Sloan, a melanoma consumer with 10 years' advocacy experience, our Consumer Advisory Panel includes members from metropolitan and regional towns throughout Australia and a representative from New Zealand.

During the year, the Consumer Advisory Panel held four meetings. Members also:

- Contributed to the development of seven new research proposals
- Represented Melanoma and Skin Cancer Trials at the launch of the Parliamentary Friends of Melanoma and Skin Cancer Awareness in Canberra
- Presented at the 2023 Melanoma and Skin Cancer Trials Annual Scientific Meeting
- Supported Melanoma and Skin Cancer Trials by networking with clinicians, industry and consumers at the 2023 Annual Scientific Meeting
- Represented Melanoma and Skin Cancer Trials at the 2023 Australasian Melanoma Conference

- Presented at the 2023 Australasian Ocular Melanoma Alliance Summit
- Attended Melanoma and Skin Cancer Trials Board strategic planning days
- Attended Melanoma and Skin Cancer Trials Discipline-Specific Advisory meetings for Dermatology, Medical Oncology, Nursing, Allied Health, Public Health and Primary Care, Australasian Merkel Cell Carcinoma Interest Group, and the Australasian Ocular Melanoma Alliance
- Represented Melanoma and Skin Cancer Trials at community events promoting skin cancer awareness in Sydney and Melbourne
- Supported communication of Melanoma and Skin Cancer Trials research, achievements, and fundraising on social media

This year we farewelled Paul White from the Consumer Advisory Panel. Paul is a melanoma survivor and was the Consumer Advisory Panel's Deputy Chair and a Board member with Melanoma and Skin Cancer Trials from 2014. Paul's lived experience with melanoma has motivated his work with us, and we thank him for consistently advocating for patients.

We also farewelled Anne Gately from the Consumer Advisory Panel. Anne has been incredibly effective lobbying the advertising and media industries to stop the use of imagery and messaging that glamourises tanning. We wholeheartedly support Anne as she continues this important work.

During the year we welcomed three new members. Tara Fullston is a stage IV melanoma survivor who has participated in the CHARLI clinical trial coordinated by Melanoma and Skin Cancer Trials. Prof Jonathan Pincus and Wayne Lieberman joined as Merkel cell carcinoma consumer representatives, and both have also worked with our Australasian Merkel Cell Carcinoma Interest Group (AMIGOs).

We also thank the many consumers we are in regular contact with, who are always willing to provide their valuable insights and contribute to our work. In particular, we thank Susan Vine for supporting our ocular melanoma clinical research and events.



Consumer Advisory Panel (As of 30 June 2023)



Alison Button-Sloan
Chair, VIC
Melanoma, basal cell carcinoma
and squamous cell carcinoma



Paul White
Deputy Chair, VIC
MASC Trials Board member
Melanoma



Michelle Taylor
NSW
Uveal melanoma



Anne Gately
NSW
Metastatic melanoma



Deborah Butler
QLD
Metastatic melanoma, basal cell
carcinoma and squamous cell
carcinoma



Prof John Pincus
SA
Merkel cell carcinoma



Wayne Lieberman
QLD
Merkel cell carcinoma



Tara Fullston
WA
Metastatic melanoma



Ron Murray
Auckland, NZ
Metastatic melanoma, basal cell
carcinoma and squamous cell carcinoma

**We thank the many consumers who
contribute to our work and provide
valuable insights.**

Melanoma trials

Melanoma (skin)



**3rd most commonly
diagnosed cancer in
Australia**



**17,000+ Australians
diagnosed with invasive
melanoma each year**



**1,400+ Australian deaths
each year**



**Australia and New
Zealand have the highest
incidence of melanoma in
the world**



**“This early detection
trial will provide the
evidence required
to determine if
Melanoma Surveillance
Photography should be
covered by Medicare.”**

A/Prof Victoria Mar,
IMAGE trial Study Chair

02.19 IMAGE

Spotting melanoma early with surveillance photography

Early detection is one of the most effective tools in the fight against melanoma. The IMAGE clinical trial, led by A/Prof Victoria Mar, is examining the use of 2D and 3D Melanoma Surveillance Photography (MSP), which involves photographing the entire skin surface as well as individual moles, in the surveillance of people at high risk of melanoma. Sequential photos can be compared to detect change, a hallmark of melanoma.

MSP will be compared to standard clinical monitoring to determine which method results in fewer ‘just in case’ biopsies in patients at high and very-high risk of melanoma.

The outcomes of the IMAGE trial will also provide the Australian Government with the high-quality evidence required to decide if MSP should be covered by Medicare. With each imaging session currently costing up to \$450, MSP is out of reach for many Australians.

The IMAGE trial was originally awarded \$2,416,998 from the Medical Research Future Fund’s Targeted Health System and Community Organisation Research initiative. The trial is sponsored by Monash University and coordinated by our Melanoma and Skin Cancer Research Centre within the School of Public Health and Preventive Medicine.

Yearly update

This year, one new site joined the trial, bringing the total number of sites to 12. We enrolled 340 new participants and reached total recruitment of 670 participants. The trial closed to recruitment on 17 April 2023, with all participants now being followed for the next two years. Data for participants enrolled in a sub-study investigating biopsy rates prior to diagnosis of melanoma is being prepared for analysis. This year the IMAGE trial had a protocol paper published in the *Trials Journal* *BioMed Central*.

More information

masc.org.au/image



**Read Lisa, Jenny
and Vikki’s patient
stories on pages
20-21**



“The results of this global effort will help determine the best surgical treatment for stage II melanoma.”

Prof Michael Henderson,
MelMarT-II trial Co-Study Chair



“We are confident this trial will deliver a consensus on melanoma excision margin size for the international medical community.”

Prof Marc Moncrieff,
MelMarT-II trial Co-Study Chair



Read Stuart's patient story on pages 10 - 11



02.18 MelMarT-II

International trial to determine optimal surgical excision margin

Patients with primary cutaneous melanoma – where the cancer cells have penetrated deeply into the skin but haven't spread to other parts of the body – undergo surgery to remove the melanoma completely. For high-risk melanoma patients, their doctor's decision to use either a 1 cm or 2 cm excision margin around the melanoma could impact their quality of life and survival.

A larger excision margin can lead to complex surgical reconstruction, poorer cosmetic appearance, post-operative complications, and impact on function. But if the excision margin is too small, the melanoma might return or spread.

Currently there is no high-quality clinical trial evidence or consensus in the medical community about the optimal melanoma excision margin size for stage II melanoma. The evidence available suggests a 1 cm margin is reasonable. The Melanoma Margins Trial, MelMarT-II, will determine whether a 1 cm or a 2 cm margin is best and provide certainty for melanoma patients and their doctors in deciding the most effective treatment.

Coordinated by Melanoma and Skin Cancer Trials, the randomised controlled surgical trial will study almost 3,000 patients across Australia, the United Kingdom, the USA, Canada, New Zealand, the Netherlands, Sweden, and Slovenia. Leading this international trial together are Prof Michael Henderson in Australia and Prof Marc Moncrieff in the United Kingdom.

The MelMarT-II trial was originally awarded \$2,766,610 from the Australian National Health and Medical Research Council. Additional funding for international trial activity has been provided by national funding organisations in other countries, including the Canadian Institutes of Health Research, UK National Institute for Health Research Health Technology Assessment, and US National Cancer Institute. The trial is sponsored by Melanoma and Skin Cancer Trials. Its collaborative partners are Peter MacCallum Cancer Centre, Norfolk and Norwich University Hospital, Canadian Cancer Trials Group, SWOG Cooperative Group, and Zuyderland Medical Center.

Yearly update

This year, 99 new sites joined the trial, bringing the total number of sites to 138. We enrolled 703 new participants, bringing the total to 1,354 (including 182 participants from the pilot study) from a target enrolment of 2,998 participants. We now have MelMarT-II trial sites across eight countries.

Boosting this international effort has been the rapid activation of 86 trial sites in the USA through the National Cancer Institute's National Clinical Trials Network (NCI-NCTN) SWOG Cooperative Group. With SWOG's support, we aim to open over 100 sites across the USA.

Melanoma and Skin Cancer Trials also raised \$4,003 for the trial as part of its end of financial year fundraising appeal.

More information

masc.org.au/melmart-ii





“This clinical trial is testing a cost-effective and accessible drug that could reduce the growing problem of heart disease in melanoma survivors.”

**Prof Stephen Nicholls,
SOCRATES trial Study Chair**

14.20 SOCRATES

Preventative treatment for melanoma patients at risk of heart disease

Immunotherapy drugs are effective in treating metastatic melanoma but can cause heart-related side-effects such as increased cholesterol deposits in heart arteries which could lead to heart attacks. Although immunotherapy has dramatically improved cancer outcomes, further research is necessary to tackle the heightened risk of heart disease and its effect on patients who are living longer following treatment.

Commencing in 2022, the SOCRATES trial is testing whether a statin, a common cholesterol-lowering drug, can prevent heart disease in melanoma patients who are being treated with immunotherapy. If successful, this treatment could improve long-term outcomes and survival rates for many melanoma patients.

Led by the Director of the Monash Victorian Heart Institute, Prof Stephen Nicholls, the trial aims to determine the effect of Atorvastatin, a commonly prescribed statin drug, on the progress of atherosclerosis of the heart in melanoma patients treated with immunotherapy.

As part of this clinical trial, images of the heart will be taken over time using computed tomography (CT) scans of heart arteries.

The SOCRATES trial represents a unique and much needed collaborative effort between oncology, dermatology, and cardiology specialities to address an emerging need in melanoma and long-term cancer survivorship care.

SOCRATES was awarded \$1,600,000 from the Federal Government’s Medical Research Future Fund. The trial is sponsored and coordinated by the Victorian Heart Institute at Monash University, with assistance from Melanoma and Skin Cancer Trials.

Yearly update

SOCRATES opened its first site at Monash Medical Centre in December 2022, followed by Cabrini Hospital. The trial’s first regional site opened in June 2023 at Latrobe Regional Health in Traralgon, enabling eligible melanoma patients to access the trial without travelling to Melbourne. The randomised controlled trial aims to enrol 180 participants across 12 sites around Australia.

More information

masc.org.au/socrates



National impact

This year, Melanoma and Skin Cancer Trials coordinated actively recruiting trials at 43 clinical trial sites throughout Australia; 67% in metropolitan cities and towns, and 33% in regional centres.

We continue to open trial sites in regional towns to make our clinical trials more accessible to Australians living in these areas.



***Conquering melanoma and skin cancer
through clinical trials***

Melanoma: the immigrant experience in a sunburnt country



When Lisa, Jenny and Vikki immigrated to Australia in their younger years, they had no idea that the outdoor lifestyle they embraced would lead to a melanoma diagnosis later in life. As melanoma patients and residents of Far North Queensland, they now understand the importance of early detection, which is why they have joined the early detection melanoma clinical trial, IMAGE, at FNQH Skin Cancer Centre Cairns.

The IMAGE trial is studying the effectiveness of 2D and 3D Melanoma Surveillance Photography (MSP) in high-risk melanoma patients compared to usual skin surveillance. The outcomes of the IMAGE trial will also provide the Australian Government with the high-quality evidence required to decide if MSP should be covered by Medicare. A skin cancer imaging session can cost up to \$450, making MSP unaffordable for many Australians.

With Queensland having the highest rate of skin cancer in the world, FNQH Skin Cancer Centre Cairns had no problem enrolling participants into the trial. Dr Vin Rajeswaran and his team are using the Vectra 3D skin cancer imaging machine for the trial, making this state-of-the-art technology available free-of-charge to participants placed in the 3D imaging group.

Lisa's story

Lisa immigrated from Northern Ireland in 1974 when she was three years old. Coming from a cold and damp country, Lisa was encouraged to take advantage of the Australian sun and play outside as much as possible.

"Sunscreen was something you put on your nose when you went to the beach for the day. I didn't cover up in the sun, and I remember being badly sunburnt a handful of times. It wasn't until I was in my early 20s that I became more sensible when out in the sun, but nothing like the sun safety measures I take now that I have been diagnosed with melanoma," Lisa said.

A trip to the GP to seek help for insomnia led to Lisa's first melanoma diagnosis when the doctor noticed a suspicious mole on Lisa's arm. Then last year, another melanoma was found on her back during a regular skin check with Dr Rajeswaran.

"When Dr Rajeswaran invited me to participate in the IMAGE trial, I didn't hesitate. It's great that this trial is accessible to rural residents like me, where healthcare can be a challenge to obtain."

Jenny's story

Jenny immigrated to Australia from the Netherlands when she was nine years old and soon after visited the beach for the first time. Unfortunately, Jenny and her new friends didn't realise how badly Jenny would burn that day, and she ended up with a painful sunburn that she still remembers today.

"I ended up with terrible blisters, so after that sunburn I always tried to stay out of the sun," Jenny said.

For most of Jenny's adult life she's had annual skin checks, but it was a nurse assessing her for an operation who noticed the suspicious mole on her elbow and encouraged her to get it checked.

"It was a melanoma and a huge chunk was taken out of my elbow, but at least it was caught early. Melanoma is so prevalent, especially in Far North Queensland, so I am happy to participate in the IMAGE trial as this early detection research is very important."



Melanoma is so prevalent in Far North Queensland so I am happy to participate in the IMAGE trial as this early detection research is very important.”

Jenny,
IMAGE trial participant

Dr Vin Rajeswaran, Jenny and Peta Beattie

Vikki's story

Vikki moved ‘across the ditch’ from New Zealand to Australia when she was 21. Although she had annual skin checks, it was a strange spot on her leg that prompted her to make an appointment to see Dr Rajeswaran at FNQH Cairns. While the spot on her leg concerned Vikki, it was an unusual spot on her shoulder that worried Dr Rajeswaran, and after a biopsy, was confirmed to be a melanoma. Since then, Vikki has had another melanoma removed, and has lesions on her arm and face that she is treating with a topical skin cancer cream.

“I’m so grateful that I got my skin checked when I did so that my melanomas and skin cancers could be caught and treated early. As part of the IMAGE trial, I am pleased to contribute to research aimed at improving early melanoma detection.”



Vikki

Merkel cell carcinoma trials

Rare, highly aggressive neuroendocrine skin cancer



Australia's deadliest form of skin cancer



300 Australians diagnosed each year



Australia has the world's highest incidence of Merkel cell carcinoma



“The outcomes of the I-MAT trial may influence future treatment strategies worldwide for patients with this rare, but often lethal cancer.”

Dr Wen Xu,
I-MAT trial Study Chair
Australasian Merkel Cell Carcinoma
Interest Group (AMIGOs) Chair

03.18 I-MAT

Trial to stop rare, lethal cancer in its tracks

Merkel cell carcinoma - a rare, highly aggressive neuroendocrine skin cancer that metastasises very quickly - is the most lethal form of skin cancer. Even when diagnosed early, Merkel cell carcinoma has a high risk of returning, with up to 50% of patients experiencing recurrence within two years.

Immunotherapy has revolutionised treatments for melanoma, and this approach is now being tested in early-stage Merkel cell carcinoma patients.

The I-MAT trial, led by Dr Wen Xu, is giving patients with stage I-III Merkel cell carcinoma the immunotherapy drug, Avelumab, after their initial surgery and / or radiotherapy for the cancer to improve their cure rates.

The trial will provide high-quality data to determine if a six-month regimen of Avelumab is well-tolerated and can eliminate residual microscopic cancer cells, thus reducing the risk of the cancer reoccurring and improving cure rates for patients with early-stage Merkel cell carcinoma.

This phase II, prospective, randomised, placebo-controlled, multicentre trial is enrolling participants across Australia. To ensure a true representation of Merkel cell carcinoma patients in the community, the trial is open in most capital cities and the regional towns of Newcastle, Port Macquarie, Wollongong, Southport, Bundaberg, Cairns, Mackay, and Townsville.

The I-MAT trial was originally awarded \$1,632,095 from the Medical Research Future Fund's Rare Cancers Initiative with top-up funding from Merck Healthcare. The trial is sponsored by Melanoma and Skin Cancer Trials.

Yearly update

This year, two new sites joined the trial, bringing the total number of sites to 19. We enrolled 34 new participants, bringing the total to 79 from a target enrolment of 132. The trial sites we opened this year were on the Gold Coast and in the regional New South Wales town of Wollongong.

More information

masc.org.au/i-mat



Read John's patient story on page 30



“Metastatic Merkel cell carcinoma is highly responsive to radiotherapy and radiation has been shown to enhance the anti-tumour effects of immunotherapy, so there is a strong rationale that either approach could amplify the effect of immunotherapy.”

A/Prof Sandhu,
GoTHAM trial Study Chair

10.17 GoTHAM

World first trial to test new treatment combination

Australia has the highest incidence of Merkel cell carcinoma in the world, although it is still considered a rare disease compared to other skin cancers such as melanoma.

In a world first, A/Prof Shahneen Sandhu is leading a trial that hopes to find a novel treatment combination for patients who have developed metastatic Merkel cell carcinoma. The trial is testing the immunotherapy drug, Avelumab, in combination with either radionuclide therapy or external beam radiotherapy.

The high-quality evidence gathered from this clinical trial will provide assurance to oncology teams that combining Avelumab with either radionuclide therapy or radiotherapy for metastatic Merkel cell carcinoma patients will yield the best possible results.

The Australia-wide multicentre, phase Ib/II trial is seeking to enrol up to 38 participants and has six trial sites open nationally.

The GoTHAM trial was funded via the Medical Research Future Fund's Rare Cancers Initiative with top-up funding from Merck Healthcare.

Yearly update

The GoTHAM trial continues to operate across six sites, with plans to open sites in regional Australia. Seven new participants were enrolled, bringing the total to 15. Due to the rarity of metastatic Merkel cell carcinoma, it is challenging to find the number of participants required to produce the evidence necessary for this new treatment option.

More information

masc.org.au/gotham



Read Allen's patient story on pages 24 - 25

Clinical trial helps adventurer overcome rare skin cancer

When Allen Schnitzerling was diagnosed with Merkel cell carcinoma – a rare but highly aggressive skin cancer – his prognosis was dire. But after putting his faith in his doctors and their “special soup”, as he affectionally calls his treatment combination, Allen is now planning adventurous holidays with his wife.

Growing up on a cane farm outside of Cairns, Allen dreamt of following in his father’s footsteps and working the land in the foothills of the stunning Wooroonooran National Park’s lush mountains.

But at the insistence of his parents, Allen pursued another of his passions, carpentry. Allen started his own business and then, at the age of 23, left his small hometown for Gladstone, which was experiencing an aluminium boom.

And so began an adventurous life that took Allen across the country – and around the world – and introduced him to his wife, Margaret.

But a life of constructing houses under the hot Australian sun left Allen peppered with sunspots, which he monitored and treated as required.

Small spot diagnosed as a rare, deadly skin cancer

It was in 2020, at the age of 78, that Allen noticed a small, firm, purplish-red mark on his leg that he dismissed as being related to a recent fall.

“I was seeing my GP to have another skin cancer removed when they noticed the mark and suspected it might be more malign than just a reminder of my accident.”

A biopsy soon confirmed that Allen was one of the 300 Australians to be diagnosed each year with a highly aggressive Merkel cell carcinoma. Shortly after, he was rushed into emergency surgery to remove the cancer and lymph nodes in his groin. Allen then underwent a course of radiotherapy.

“I was quite hopeful after that initial treatment – you have to be, despite the scary statistics – but about a year later I received the bad news that the cancer had returned.”

Allen was promptly offered a spot in the GoTHAM trial, which is investigating the effectiveness of combining radiotherapy with immunotherapy for treating metastatic Merkel cell carcinoma.

“I was so grateful to be offered a place on the GoTHAM trial. I’ve always put my trust in professionals, particularly when it comes to anything medical, so I looked them dead in the eye and said, ‘I’m your patient, you go for it’ – and I’m so glad I did.”

“At my first trial appointment, I told the medical staff that I hope they can keep me alive a bit longer, because I’ve got a few more things I want to do and more adventures to go on with my beautiful wife.”

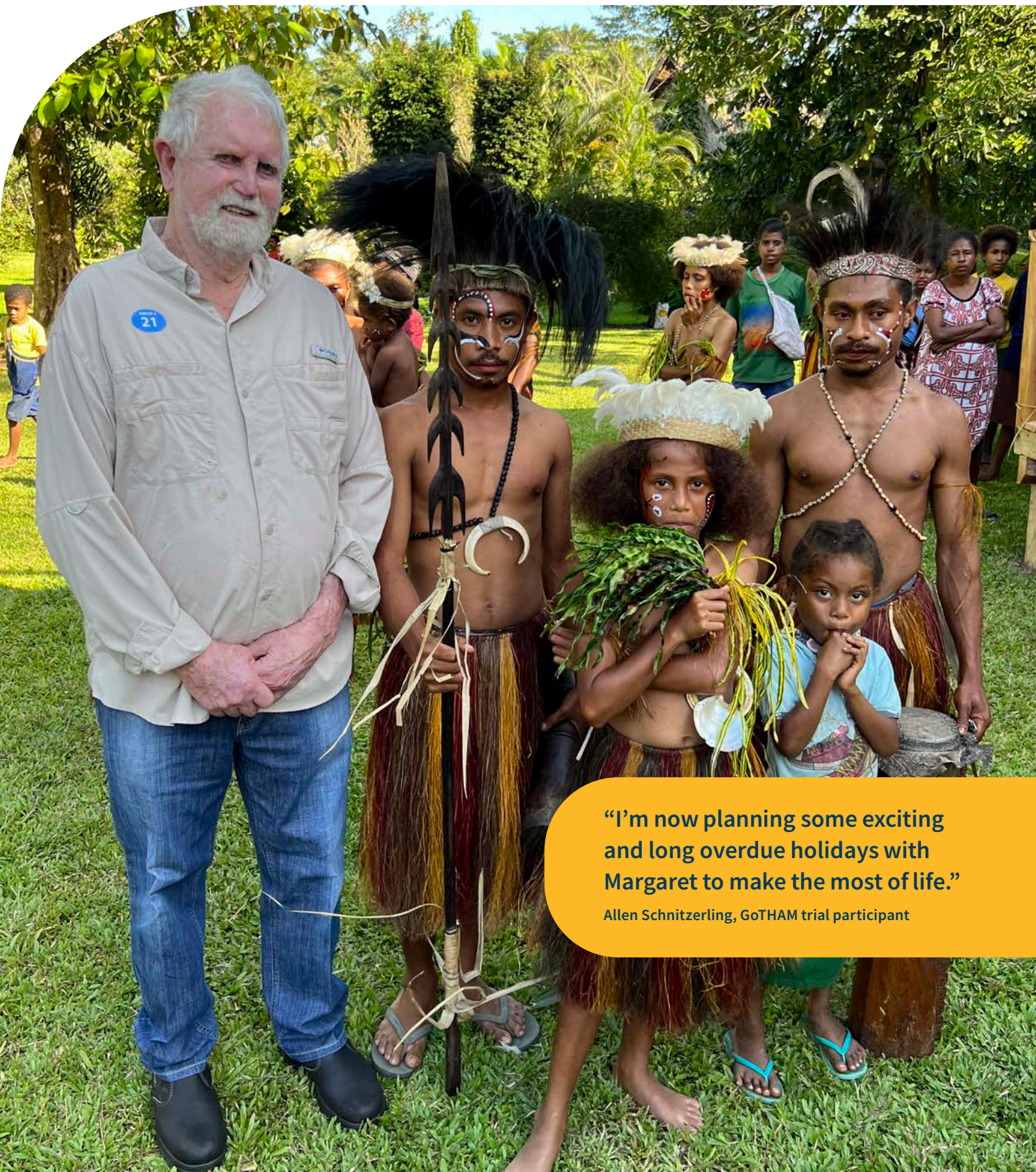
Cancer free and planning holidays

Four months after his first treatment session, Allen received some positive news – a positron emission tomography (PET) scan revealed he was cancer free.

“Hearing that was probably the most emotional I’d gotten throughout this whole thing. I was so overwhelmed and overjoyed that I have a bit more time left. And while they can’t say for certain that the cancer is totally gone, I’m planning some exciting and long overdue holidays with Margaret to make the most of life.”

With the blessing of the GoTHAM team (and some shuffling of appointments) Allen and Margaret embarked on a cruise around Papua New Guinea in mid 2023 – somewhere they’ve wanted to visit since they were young.

And with a European river cruise on the horizon, Allen is excited for a future made possible thanks to innovative treatments developed through clinical trials.



“I’m now planning some exciting and long overdue holidays with Margaret to make the most of life.”

Allen Schnitzerling, GoTHAM trial participant

Uveal melanoma clinical research

Rare form of melanoma in the eye



200 Australians diagnosed each year



36 Australians die each year



25% of patients require enucleation (removal of the eye)



“The registry will gather important patient data to improve treatments and clinical guidelines for this deadly cancer.”

Prof Anthony Joshua,
Australian Uveal Melanoma
Registry Lead Investigator
Australasian Ocular Melanoma
Alliance Chair

07.17 Uveal Melanoma Registry

Informing research and new treatments

Uveal melanoma is a rare and aggressive form of ocular melanoma for which there are very few accepted treatments. Uveal melanoma is clinically and biologically different from the more common skin melanoma.

This real-world registry is helping to identify predictive clinical features, document the natural history of uveal melanoma, and collect information about clinical management. The registry was made possible through our collaboration with Pulse Infoframe, a real-world evidence generation, health informatics and insights company that supports our ecosystem across patients and researchers. Bristol Myers Squibb has also contributed funding to the Australian registry.

This multicentre Uveal Melanoma Registry will generate clinical and biomarker data that can be used to support drug development and pricing reimbursement. Patients can also provide direct feedback, offering a holistic view of the impact of uveal melanoma and its treatments.

Yearly update

Established in May 2021, three new sites joined the Australian registry this year, bringing the total number of sites to eight. The registry enrolled 94 participants this year, bringing the total number of participants to 239. Work continues to expand the registry with an additional site planned for Auckland, New Zealand, and continued collaboration with our partners in Canada.

Melanoma and Skin Cancer Trials also raised \$7,000 for the registry through its 2022 Christmas fundraising appeal. This effort was greatly supported by Consumer Advisory Panel member and ocular melanoma consumer advocate, Michelle Taylor.

More information

masc.org.au/uveal-melanoma-registry-omni



Network of experts

Special interest groups

Australasian Ocular Melanoma Alliance

The Australasian Ocular Melanoma Alliance (AOMA) works to improve care and treatment for ocular melanoma patients in Australia and around the world, and to further research into this rare form of melanoma.

AOMA was founded in 2017 and includes ophthalmologists, surgeons, medical and radiation oncologists, pathologists, allied health professionals, scientists, researchers, and consumer representatives from across Australia and New Zealand. AOMA is chaired by Prof Anthony Joshua, a medical oncologist from Sydney.

Yearly update

During the year, AOMA met twice to develop ideas for new uveal / ocular melanoma trials, discuss current research, and review grant opportunities. The group also discussed a public commentary response including letters of support coordinated by Melanoma and Skin Cancer Trials to support the Pharmaceutical Benefits Advisory Committee review of Tebentafusp.

The annual AOMA Summits are Australasia's premier ocular melanoma cross-disciplinary meetings featuring presentations from world-leading ocular melanoma experts and consumers with lived experience of the cancer. AOMA Summits were held as virtual meetings on 30 July 2022 and 24 June 2023. Each meeting had over 200 registrations, with the 2023 meeting being broadcast to 19 countries. Videos from each meeting are available at:

- masc.org.au/aoma-summit-2023
- masc.org.au/aoma-2022



More information

aoma.org.au



Australasian Merkel Cell Carcinoma Interest Group

The Australasian Merkel Cell Carcinoma Interest Group (AMIGOs) is a network of specialists across the globe working to advance the treatment and care of patients with Merkel cell carcinoma through clinical trials, basic and translational research.

AMIGOs was formed in 2017 and includes clinicians and researchers representing medical oncology, radiation oncology, surgical oncology, pathology, genetics, imaging and laboratory-based research, and consumer advocates. The group was originally led by Prof Gerald Fogarty, and is now chaired by Dr Wen Xu, a medical oncologist from Brisbane.

Yearly update

During the year, AMIGOs met twice to develop ideas for new Merkel cell carcinoma trials, review grant opportunities, and report on Merkel cell carcinoma trials in the Melanoma and Skin Cancer Trials portfolio. The group also discussed the need for a national Merkel cell carcinoma patient registry and other areas of unmet needs.



AMIGOs

Australasian Merkel Cell Carcinoma
Interest Group

More information

amigos.org.au



Discipline-Specific Advisories

Melanoma and Skin Cancer Trials Discipline-Specific Advisories are forums for researchers, clinicians, and patients to share ideas and drive progress to improve how melanoma and skin cancer is prevented, diagnosed, and treated.

Our Discipline-Specific Advisories welcome clinicians and researchers from a range of specialities and disciplines. We aim to boost Australia-wide engagement, representation across disciplines, and to generate clinical research concepts and new opportunities to collaborate. We currently have 247 Discipline-Specific Advisory members.

Yearly update

During the year, Melanoma and Skin Cancer Trials facilitated 20 Discipline-Specific Advisory meetings. The outcomes of these meetings included:

- Progress updates of active trials in the Melanoma and Skin Cancer Trials portfolio
- Discussion on areas of unmet clinical research needs within each Advisory's discipline
- Provision of peer review and feedback for new research proposals prior to endorsement by Melanoma and Skin Cancer Trials
- Ranking of three new research proposals that progressed to submission to competitive funding bodies
- Formation of new multi-disciplinary collaborations including consumers partners
- The non-melanoma (keratinocyte) skin cancer focus of the 2023 Concept Development Workshop.

Dermatology	Co-Chair - Prof Pascale Guitera Co-Chair - Prof Nikolas Haass
Medical Oncology	Chair – Dr Wen Xu Deputy Chair – Dr Miles Andrews
Radiation Oncology	Chair – Prof Angela Hong Deputy Chair – A/Prof Tim Wang
Surgical Oncology	Chair – Dr John Spillane
Skin Cancer	Chair – Prof Kiarash Khosrotehrani Deputy Chair – Dr Rahul Ladwa
Nursing, Allied Health, Public Health and Primary Care	Chair – Prof David Whiteman Deputy Chair – Prof Monika Janda



Many of our Discipline-Specific Advisory members attended the 2023 Melanoma and Skin Cancer Trials Annual Scientific Meeting in Brisbane.

An intrepid explorer's biggest journey

John Mason spent much of his life outside in the sun, including 13 years of constant fieldwork in Papua New Guinea and then a decade living on a cruising yacht in sunny Queensland and the Northern Territory. When his doctor found a malignant tumour below his left ear, John felt that removal and recovery would be a routine process.

A month after having the lump surgically removed, John, aged 72, made the long journey from his home in regional Bundaberg to Brisbane's Princess Alexandra Hospital, where he was scheduled to begin chemotherapy.

But when a doctor John had never met before sombrely ushered him into a small consultation room, he realised something was wrong.

"The doctor told me that I had a Merkel cell carcinoma, a rare and aggressive form of skin cancer. I had never heard of it before, so I asked what the survival rate was. He looked me square in the eyes and said earnestly "Frankly, the numbers aren't good, John."

The doctor who saw John that morning was Dr Wen Xu, Chair of the Australasian Merkel Cell Carcinoma Interest Group (AMIGOs) and lead investigator of the I-MAT clinical trial investigating a treatment involving the immunotherapy drug, Avelumab, in earlier stages of Merkel cell carcinoma.

"When Dr Xu told me about the I-MAT trial, I could hardly believe it. Not only would I get free access to an otherwise prohibitively expensive treatment, but I'd get regular monitoring and support. In the space of minutes, I'd gone from the crushing low of my diagnosis to realising how lucky I was to meet Dr Xu and receive the treatment that I'm getting."

After a few formalities were completed, John was soon enrolled in the I-MAT trial and, after a course of radiotherapy, commenced immunotherapy.

John received his treatment in Bundaberg, as the I-MAT trial has several regional sites to ensure more Australians can access the trial.

"I was so grateful that I didn't need to travel to Brisbane for immunotherapy, as that would have been a huge complication. When you are going through something as stressful as a cancer diagnosis, you just want a bit of normality. Being able to access the treatment locally has been hugely positive for me."



An incredible support team

John tolerated the trial treatment well, experiencing very few side-effects. Now, having finished the treatment, he is focused on completing the PhD he commenced before his diagnosis. John is researching sustainability issues amongst volunteer firefighters.

"I've long been intrigued by what motivates these local heroes to put their lives on the line, and through my treatment I've met some other inspirational heroes. From Dr Xu through to everyone at Genesis Care and Cancer Care in Bundaberg, I know I am in the best hands possible.

"Most importantly, I'd encourage everyone to be more careful in the sun. I certainly wasn't careful enough and it's caught up with me. But if you do get a scary prognosis, it doesn't have to be the end – and thanks to modern medicine and research, it can actually be a new beginning. Hold fast, be brave, and have faith in the skills of the incredible health professionals assisting you."

Sharing his experience with others

John shared his experience of the I-MAT trial and his perspectives as a Merkel cell carcinoma patient at the Melanoma and Skin Cancer Trials Annual Scientific Meeting in Brisbane on 23 March 2023. During his presentation, John reminded clinicians of the impact they can have on their patients, and the value of getting to know their patients for improved care.

Current research

Recruiting trials

Trial No.	Trial Name	Trial Official Title	Principal Investigator	Lead Site	Sponsor / Coordinating Centre	Funding
10.17	GoTHAM	A phase Ib/II study of combination Avelumab with peptide receptor radionuclide therapy or conventional fractionated radiotherapy in patients with metastatic Merkel cell carcinoma	A/Prof Shahneen Sandhu	Peter MacCallum Cancer Centre, VIC	Melanoma and Skin Cancer Trials	<ul style="list-style-type: none"> Medical Research Future Fund – Low Survival Cancers and Diseases Merck Healthcare
03.18	I-MAT	A randomised, placebo-controlled, phase II trial of adjuvant Avelumab in patients with stage I-III Merkel cell carcinoma	Dr Wen Xu	Princess Alexandra Hospital, QLD	Melanoma and Skin Cancer Trials	<ul style="list-style-type: none"> Medical Research Future Fund – Rare Cancers, Rare Diseases and Unmet Need Merck Healthcare
02.18	MelMarT-II	A phase III, multicentre, multinational randomised control trial investigating 1 cm v 2 cm wide excision margins for primary cutaneous melanoma	Prof Michael Henderson (Aus) Prof Marc Moncrieff (UK)	Peter MacCallum Cancer Centre, VIC	Melanoma and Skin Cancer Trials	<ul style="list-style-type: none"> National Health and Medical Research Council
07.17	Uveal Melanoma Registry	Uveal Melanoma Registry (A Prospective Natural History Study in Uveal Melanoma)	Prof Anthony Joshua	St Vincent's Hospital, NSW	Melanoma and Skin Cancer Trials	<ul style="list-style-type: none"> Pulse Inframe Bristol Myers Squibb
14.20	SOCRATES	Statins and progression of Coronary atherosclerosis in melanoma patients Treated with checkpoint inhibitorS	Prof Stephen Nicholls	Monash Health, VIC	Monash University, Monash Victorian Heart Institute, and Melanoma and Skin Cancer Research Centre	<ul style="list-style-type: none"> Medical Research Future Fund

Trials in start-up

Study No.	Study Name	Study Official Title	Principal Investigator	Lead Site	Sponsor / Coordinating Centre	Funding
01.21	SiroSkin	Trial of sirolimus cream in organ transplant recipients to prevent skin cancer	Prof Kiarash Khosrotehrani	Prince Charles Hospital, QLD	Monash University / Melanoma and Skin Cancer Research Centre	<ul style="list-style-type: none"> Medical Research Future Fund
05.21	BETTER	Bevacizumab and immune checkpoint inhibitors plus hypofractionated stereotactic radiotherapy for the treatment of symptomatic melanoma brain metastases	A/Prof Tim Wang Dr Malaka Ameratunga	Alfred Hospital, VIC	Monash University / Melanoma and Skin Cancer Research Centre	<ul style="list-style-type: none"> Australian Skin Cancer Foundation

Active trials closed for recruitment

Trial No.	Trial Name	Trial Official Title	Principal Investigator	Lead Site	Sponsor	Funding
02.19	IMAGE	Melanoma surveillance photography to improve early detection of melanoma in very-high and high risk patients	A/Prof Victoria Mar	Alfred Hospital, VIC	Monash University / Melanoma and Skin Cancer Research Centre	<ul style="list-style-type: none"> Medical Research Future Fund - Targeted Health System and Community Organisation Research Grant Opportunity
01.15	CHARLI	A phase Ib/II trial of Ipilimumab-Nivolumab-Denosumab and Nivolumab-Denosumab in patients with unresectable stage III and IV melanoma	A/Prof Shahneen Sandhu	Peter MacCallum Cancer Centre, VIC	Peter MacCallum Cancer Centre	<ul style="list-style-type: none"> Bristol Myers Squibb Amgen
02.12	RADICAL	A randomised controlled multicentre trial of imiquimod versus radiotherapy for lentigo maligna when staged surgical excision with 5 mm margins is not possible, is refused, or fails	Prof Pascale Guitera	Melanoma Institute Australia, NSW	Melanoma and Skin Cancer Trials	<ul style="list-style-type: none"> Cancer Australia - Priority-driven Collaborative Cancer Research Scheme Project Grant, and philanthropic funding
01.12	EAGLE FM	Evaluation of groin lymphadenectomy extent for metastatic melanoma – A randomised phase III trial to evaluate survival, morbidity, and quality of life	Prof Andrew Spillane	Royal North Shore Hospital, NSW	Melanoma and Skin Cancer Trials	<ul style="list-style-type: none"> Cancer Council NSW Friends of the Mater Foundation
03.12	MelMarT (Pilot)	A phase III, multicentre, multinational randomised control trial investigating 1 cm v 2 cm excision margins for primary cutaneous melanoma	Prof Michael Henderson (Aus) Prof Marc Moncrieff (UK)	Peter MacCallum Cancer Centre, VIC	Melanoma and Skin Cancer Trials	<ul style="list-style-type: none"> Cancer Council NSW Friends of the Mater Foundation
01.09	RTN2	A randomised trial of postoperative radiation therapy following wide excision of neurotropic melanoma of the head and neck	A/Prof Matthew Foote	Princess Alexandra Hospital, QLD	Melanoma and Skin Cancer Trials	<ul style="list-style-type: none"> Cancer Australia Priority-driven Collaborative Research Scheme Project Grant
01.07	WBRTMel	Whole brain radiotherapy following local treatment of intracranial metastases of melanoma – A randomised phase III trial	Prof Gerald Fogarty	St Vincent's Hospital, NSW	Melanoma and Skin Cancer Trials	<ul style="list-style-type: none"> Cancer Australia Priority-driven Collaborative Research Scheme Project Grant

Completed trial

Trial No.	Trial Name	Trial Official Title	Principal Investigator	Lead Site	Sponsor	Funding
04.17	SMARTI	A pilot study of an artificial intelligence system as a diagnostic aid for better skin cancer management	A/Prof Victoria Mar	Alfred Hospital, VIC	Monash University / Melanoma and Skin Cancer Research Centre	<ul style="list-style-type: none"> Victorian Medical Research Acceleration Fund MoleMap

Completed research study

Study No.	Study Name	Study Official Title	Principal Investigator	Lead Site	Sponsor	Funding
05.19	Supporting People with Cancer Project	Improving melanoma and skin cancer awareness in regional and rural Australia	A/Prof Victoria Mar	N/A	Melanoma and Skin Cancer Trials	<ul style="list-style-type: none"> Cancer Australia – Supporting People with Cancer Grant Initiative

Publications

Journal of American Academy of Dermatology

Felmingham, C., Pan, Y., Kok, Y., Kelly, J., Gin, D., Nguyen, J., Goh, M., Chamberlain, A., Oakley, A., Tucker, S., Berry, W., Darling, M., Jobson, D., Robinson, A., de Menezes, S., Wang, C., Willems, A., McLean, C., Cranwell, M., Adler, N., Wada, M., Foley, P., Brack, J., Cumming, S., Byars, G., Bowling, G., Z., Haskett, M., Wolfe, R., Mar, V. (2023) Improving Skin cancer Management with ARTificial Intelligence (SMARTI): a pre-post intervention trial of an Artificial Intelligence system used as a diagnostic aid for skin cancer management in a real-world specialist dermatology setting. *Journal of the American Academy of Dermatology*, 88 (5), 1138-1142. <https://doi.org/10.1016/j.jaad.2022.10.038>

Conference presentations

Joshua, A., Finally! Progress in uveal melanoma, MASC Trials Annual Scientific Meeting, 23 March 2023, Brisbane

Khosrotehrani, K., SiroSkin trial: reducing the burden of skin cancers in organ transplant recipients, MASC Trials Annual Scientific Meeting, 23 March 2023, Brisbane

Lau, P., et al. A Phase Ib/II Trial of Ipilimumab-Nivolumab-Denosumab or Nivolumab-Denosumab in Patients with Unresectable Stage III and IV Melanoma: The CHARLI Trial (CHARLI study). American Society of Clinical Oncology 2023, 4 June 2023, Chicago, Illinois, USA

Lee, T., et al. Evaluation of leg lymphoedema after inguinal and ilio-inguinal lymphadenectomy for melanoma (EAGLE FM study). Australasian Melanoma Conference, 24-25 March 2023, Brisbane

Luckett, T., Content validation of quality of life questionnaire items for people with metastatic uveal melanoma, MASC Trials Annual Scientific Meeting, 23 March 2023, Brisbane

Luckett, T., Invitation to participate in development of Quality of Life tool for people with metastatic uveal melanoma, Australasian Ocular Melanoma Alliance Virtual Summit, 30 July 2022

Mar, V., Melanoma clinical trials for early diagnosis and surveillance, MASC Trials Annual Scientific Meeting, 23 March 2023, Brisbane

Moncrieff, MD., Henderson, MA., Mammen, MJV. MelMarT-II Trial Investigator Meeting. International Conference on Surgical Cancer Care, 23 March 2023, Boston, Massachusetts, USA

Trials Journal

Yan, M. K., Cust, A. E., Soyer, H. P., Janda, M., Loewe, K., Byars, G., Fishburn, P., White, P., Mahumud, R. A., Saw, R. P. M., Herschtal, A., Fernandez-Penas, P., Guitera, P., Morton, R. L., Kelly, J., Wolfe, R., Mar, V. J. (2023). Study protocol for a randomised controlled trial to evaluate the use of melanoma surveillance photography to Improve early detection of Melanoma in ultra-high and high-risk patients (the IMAGE trial). *Trials*, 24 (236). <https://doi.org/10.1186/s13063-023-07203-5>

O'Day, R., Audit of uveal melanoma biopsies in Victoria, Australasian Ocular Melanoma Alliance Virtual Summit, 30 July 2022

Pinkham, MB., et. al. Results from a randomised trial of post-operative radiation therapy following wide excision of neurotropic melanoma of the head and neck (RTN2 trial). Australasian Melanoma Conference, 24-25 March 2023, Brisbane

Sandhu, S., Combination of Avelumab with Peptide Receptor Radionuclide Therapy (PRRT) or Conventional Fractionated Radiotherapy (RT) in Metastatic Merkel Cell Carcinoma (mMCC) (GoTHAM trial). Australasian Melanoma Conference, 24-25 March 2023, Brisbane

Sandhu, S., Merkel cell carcinoma clinical research, MASC Trials Annual Scientific Meeting, 23 March 2023, Brisbane

Saw, R., MelMarT-II trial: defining wide excision margins for high risk primary melanoma, MASC Trials Annual Scientific Meeting, 23 March 2023, Brisbane

Xu, W., Immunotherapy Merkel Adjuvant Trial (I-MAT) and Australasian Merkel Cell Carcinoma Interest Group (AMIGOs), MASC Trials Annual Scientific Meeting, 23 March 2023, Brisbane

Xu, W., Merkel Cell - The Role of Adjuvant and Neoadjuvant Therapies, Australasian Melanoma Conference, 25 Mar 2023, Brisbane

Vine, S., Supporting ocular melanoma patients, Australasian Ocular Melanoma Alliance Virtual Summit, 24 June 2023

Events

Annual Scientific Meeting

This year's Annual Scientific Meeting was held on 23 March 2023 as a satellite meeting of the Australasian Melanoma Conference at the Brisbane Convention and Exhibition Centre.

The sold-out event brought together 117 healthcare professionals, researchers and consumers to share the latest updates from Melanoma and Skin Cancer Trials and learn about innovative studies taking place in the field.

The meeting featured two international keynote speakers, Prof Harald Kittler from Austria, and A/Prof Sapna Patel from the USA. In addition, a stellar line up of 15 Australian speakers shared progress from our clinical trial portfolio investigating melanoma, skin cancer, Merkel cell carcinoma, uveal melanoma, and primary and supportive care.

The lived cancer experience was highlighted during the meeting, with presentations delivered by melanoma, Merkel cell carcinoma, and uveal melanoma consumers. Their presentations emphasised the importance of listening to the consumer voice throughout all stages of research and clinical care.

Following the meeting was a networking event, which encouraged all those attending to build new connections, catch up with interstate colleagues, and discuss future clinical trial plans.

Concept Development Workshop

Melanoma and Skin Cancer Trials held its first Concept Development Workshop on 9 June 2023 at the Translational Research Institute in Brisbane. During the workshop, five new skin cancer research proposals were discussed. The feedback on the proposals was invaluable, with some now having the potential to progress into grant applications.

The workshop was attended by 18 researchers in-person and online, including our Board Chair Prof Mark Shackleton, Chair of our Skin Cancer Discipline-Specific Advisory (DSA), Prof Kiarash Khosrotehrani, several experienced Queensland researchers including Prof H. Peter Soyer and Prof Monika Janda, our Consumer Advisory Panel Chair, Alison Button-Sloan, and other DSA members.

The group of dermatologists, oncologists and university researchers also received feedback on the proposals from representatives of the national technical services for Quality of Life (CQUEST) and health economics (CREST).



We are very thankful to all the sponsors of the 2023 Annual Scientific Meeting, especially our Platinum Sponsors: Medison, MSD, and Sanofi.

Plans are now underway for the 2024 meeting, which will again be held as a satellite meeting of the Australasian Melanoma Conference, this time in Sydney. For information about the 2024 Annual Scientific Meeting, go to: masc.org.au/asm-2024



Financial statement

Melanoma and Skin Cancer Trials Limited
ABN 70 626 908 512

Statement of profit and loss and other comprehensive income for the period ended 30 June 2023.

	2023 \$
Revenue	123,827
Total Revenue	123,827
Administration	8,817
Conferences and papers	1,200
Information technology, including subscriptions	9,544
Insurance	4,107
Legal	-
Printing	7,160
Publications	-
Registration and capitation fees	-
Salary support	12,974
Event Management	32,785
Travel	7,992
Total Expenses	84,579
STATEMENT OF FINANCIAL POSITION AS AT 30 JUNE 2023	
ASSETS	
CURRENT ASSETS	
Cash and cash equivalents	353,886
Accounts receivable	5,150
TOTAL CURRENT ASSETS	359,036
TOTAL ASSETS	359,036
LIABILITIES	
Accrued expense	4,002
TOTAL LIABILITIES	-
NET ASSETS	355,034
EQUITY	
Retained earnings	355,034
TOTAL EQUITY	355,034

The full Annual Financial Report and Directors Report for the year ending 30 June 2023, audited by Charterpoint, are available at www.acnc.gov.au/charity

Acknowledgments

Melanoma and Skin Cancer Trials recognises and thanks the many organisations that support our research. Their support has ensured our research continues to improve melanoma and skin cancer outcomes.

Academic Affiliate



Australian Funding Agencies and Institutions



Industry Partners



Pro Bono Suppliers



Get involved



Become a Member

Melanoma and Skin Cancer Trials membership is open to anyone who has an interest in our melanoma and skin cancer clinical trials. Applying is simple and free.

As a Melanoma and Skin Cancer Trials Member, you will join our network of 2,396 healthcare professionals, researchers and consumers who are committed to conquering melanoma and skin cancer through clinical trials. Your membership will also influence our Federal Government support and help us to expand our work that is improving how doctors prevent, diagnose, and treat melanoma and skin cancer.

Become a Member:

masc.org.au/membership



Become a corporate partner

Corporate support can take many forms. We work to ensure your partnership goals are met and that together, we produce an outcome that has real-world impact. Some ways in which we can work together include:

- Delivering new initiatives to improve the lives of melanoma and skin cancer patients
- Sponsorship of scientific events
- Support for a new or existing clinical trial
- Operational assistance through a pro bono service or product

Contact us to discuss partnership:

hello@masc.org.au



Participate in a clinical trial

Clinical trials are essential for discovering new treatments for melanoma and skin cancer. They also provide access to breakthrough medical treatments that may benefit patients with these cancers.

Learn more:

www.masc.org.au/participate



Our donors



Celebrating major donors

Foundation Club 100 celebrates our first 100 major supporters who donate \$500 or above. These important donors are helping us to expand our clinical trials so that more Australians can benefit from medical advances in melanoma and skin cancer. This year we welcomed our first Foundation Club 100 members. We still have memberships available, so please consider joining Foundation Club 100 today.

We sincerely thank the following people who joined Foundation Club 100 this year:

Aileen Boyd-Squires
Timothy Buckley
Gabrielle Byars
Matthew Cook
Justin Ganly
Stephen Kerr
Stephen Longley
A/Prof Victoria Mar
Mr Richard Martin

Anton Middendorp
David Morgan OAM
Ian Morrison
Jane Morrison
Prof Mark Shackleton
Prof Andrew Spillane
Dr Robert Teunisse
Mary Tsouvalakis
Sharon Van Buerle

Join Foundation Club 100:
masc.org.au/foundation-club-100



Australian Skin Cancer Foundation

Thanks to the fundraising efforts of the Australian Skin Cancer Foundation, we launched a new clinical trial this year focused on patients with melanoma that has spread to the brain. The Foundation kickstarted the BETTER trial with its first donation of \$100,000 in August 2022 followed by a second donation of \$110,000 in February 2023.

The funds were raised through two of the Foundation's Mission Melanoma campaigns, in which hundreds of Australians walked thousands of kilometres in the name of melanoma research.

Melanoma brain metastases is so severe and complex that many patients are unable to participate in clinical trials, resulting in limited treatment options. Current treatments, including steroids, have long-term side effects and may reduce the effectiveness of immunotherapy. The BETTER trial may offer improved quality of life for these patients.

The initial phase of the BETTER trial will commence at the Alfred Hospital in Melbourne and Westmead Hospital in Sydney. This trial would not have been possible without the Australian Skin Cancer Foundation's support.



Donate



Your donation will directly support our clinical trials

Help us to conquer melanoma and skin cancer

Every year, over 17,000 Australians are diagnosed with invasive melanoma and around 1,400 Australians will lose their life to this deadly cancer that can affect young and old.

Australian researchers have led the way in developing treatments for melanoma, and the last decade has seen remarkable breakthroughs. Clinical trials have played a critical part in this success.

The first wave of industry-driven innovation in melanoma and skin cancer treatments led by major pharmaceutical companies has receded. Although we now have a range of new therapies, we are still discovering how to optimally use these new treatments for patients and that is why our clinical trials are so important.

Giving Australians access to clinical trials

Thanks to the work of Melanoma and Skin Cancer Trials over the past 24 years, more than 7,000 patients have accessed our clinical trials that may have improved their quality of life, prevented them from undergoing debilitating treatments, and for some, given them more time with loved ones.

More funding is urgently needed

High-quality clinical trials require significant and sustained financial investment to deliver real-world results. As a not-for-profit organisation, Melanoma and Skin Cancer Trials cannot rely on government funding alone. We need your help to improve the lives of melanoma and skin cancer patients.

Donate to clinical trials

Your donation will directly support our clinical trials. You will be helping our world-leading researchers to improve melanoma and skin cancer outcomes, and to study innovative combined cancer treatments. Most importantly, you will be making a difference to the lives of melanoma and skin cancer patients across Australia and New Zealand.

Donate today at: masc.org.au/donate



Melanoma and Skin Cancer Trials Team



Melanoma and Skin Cancer Trials

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Melanoma Trials Group*

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