



# Melanoma and Skin Cancer Trials Limited



Melanoma and Skin Cancer Trials Limited

Annual Report 2019/2020



### **MASC Trials Chair**

Professor Mark Shackleton      2018– current

### **ANZMTG Chairs**

Professor Mark Shackleton      2017—2018

Professor Bryan Burmeister      2014—2017

Professor John Thompson      1999—2014

Melanoma and Skin Cancer Trials Limited was registered as an Australian Public Company, Limited by Guarantee, on 20 December 2018.

MASC Trials was formerly called the Australian and New Zealand Melanoma Trials Group (ANZMTG).

Melanoma and Skin Cancer Trials Ltd  
553 St Kilda Road Melbourne VIC 3004  
Australia

MASC Trials acknowledge the Traditional Owners of Country throughout Australia and recognise the continuing connection to lands, waters and communities. We pay our respects to Aboriginal and Torres Strait Islander cultures, and to Elders both past and present.

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## ABOUT MASC TRIALS

MASC Trials brings together a powerful network of almost 2,000 professionals who represent the many disciplines critical to our work – oncologists, surgeons, radiation specialists, nurses, allied health professionals, health economists, statisticians, research scientists, clinical research associates, data managers, patient advocates and others.

With expert support from our Advisories and our trials staff, MASC Trials leads and designs research and clinical trial development, and provides project management for multicentre, national and international collaborations.

### OUR SERVICES

The MASC Trials team can offer expertise and support across:

- New idea generation and protocol development;
- Research and clinical trial budget preparation;
- Peer review via the MASC Trials Scientific Advisory Committee and Discipline-Specific Advisories;
- Feasibility evaluation across the MASC Trials membership;
- Biostatistics and statistical modelling;
- Health economic modelling;
- Quality of Life and patient report outcome modelling;
- Consumer and patient advocacy engagement;
- Grant writing through to application submission;
- Endorsement of research studies and clinical trials;
- Access to our network to encourage participation in endorsed clinical trials; and
- Research and clinical trial education, and mentoring opportunities.

Whilst MASC Trials does not directly fund research, we support researchers in seeking funding across government, industry, and other competitive funding bodies, and the philanthropic sector.

Endorsement of research projects and clinical trial protocols by MASC Trials provides a prestigious badge of quality and has been a key factor in our past successes in competitive grant applications, approval through ethics committees, and clinical trial participation by investigators and sites worldwide.

## CHAIRMAN'S REPORT

Dear Members,

As we venture out of a COVID-19 dominated year, I am pleased to report on the achievements of 2020, which would not have been possible without the continued support and active engagement of our board of directors, network, membership, management, staff and community of supporters.

This year we have (nearly) finalised the revamped governance of MASC Trials Limited, as well as our new affiliation with Monash University via formation of the Melanoma and Skin Cancer Research Centre in the Monash School of Public Health and Preventive Medicine. These changes have placed our group in a strong and stable physical and operational position to support our members in research project development and implementation. Our restructuring commenced in 2017 and has increased opportunities to encourage, engage, collaborate and support investigator-initiated research for the ultimate benefit of people and families affected by melanoma and skin cancer. Pleasingly and to provide even greater operational stability, Monash University recently extended its partnership with MASC Trials to at least 2025.

The final changes relating to the above transitions were recently announced, particularly the conclusion of Libby Paton's role with the group after over a decade of dedicated service to our membership and the wider melanoma and skin cancer research, clinician and patient communities. Over her 12 years with and leading MASC Trials, which was of course known as the Australian and New Zealand Melanoma Trials Group (ANZMTG) when she commenced, Libby has worked tirelessly to grow the organisation into one of Australia's most respected clinical trial groups. Her collaborative approach and determination to bring together and empower the best researchers have enabled impactful and influential clinical trials that otherwise may not have been possible. Moreover, her pivotal role and tireless commitment in steering our group towards its incorporation as MASC Trials Ltd and across its transition of affiliation from the University of Sydney to Monash University steadfastly following directives set by the board have created outstanding national resources for melanoma and skin cancer patients and researchers. We formally acknowledge Libby's work in leading us over a truly transformational period and express our sincerest gratitude all she has done, both for our organisation and for melanoma and skin cancer research in general. The board and staff wish Libby all the best for her departure and in all future endeavours.

I am pleased to welcome Aileen Boyd-Squires as the incoming CEO of MASC Trials Ltd and Head of the MASC Research Centre at Monash University. Aileen brings a wealth of experience with more than 20 years in executive roles in the medical research, not-for-profit and commercial sectors and has a clear vision for the next phase of our growth. Please feel free to reach out and introduce yourself to Aileen and to understand how she will be leading us beyond 2020.

Despite the impact of the pandemic and the organisational restructuring - including the novation of research projects from other institutions to Monash University, commencement of new studies, organizational restructuring, and hiring and training new team members - the group has maintained the highest-quality clinical research standards and a keen focus on supporting its existing research commitments.

In this light, the group has continued to expand activities throughout 2020 with more staff, new trials, new recruiting sites, national and international engagements, and more academic and commercial partnerships than ever before.

I would like to take this opportunity to thank the board of directors, who give freely of their time to oversee and provide advice. Moreover, I acknowledge our management team and the great staff, who have made outstanding contributions across all areas of our activities, from late-night sessions meeting impossible grant deadlines, to collection and analyses of trial data for presentations at major conferences and in journal submissions.

MASC Trials is in an exciting period of operational consolidation and growth. I sincerely thank our members and funders (particularly Cancer Australia and Monash University) and look forward to continuing to deliver on the vision of the group to improve outcomes for melanoma and skin cancer patients and their families through the development and conduct of the high-quality research.

Sincerely



**Professor Mark Shackleton MBBS PhD FRACP**

Chair, Melanoma And Skin Cancer Trials Limited

Director of Oncology, Alfred Health

Professor of Oncology, Monash University

Clinical Research Fellow, Victorian Cancer Agency



# CEO REPORT

Dear Members,

I am pleased to report MASC Trials has continued to grow its trial activity, funding, regional and international engagement, and membership diversity and representation.

MASC Trials maintains a growing portfolio of clinical trials that address important research questions in melanoma and skin cancer field. I would like to recognise the efforts and hard work of our many researchers and collaborators, which have been essential to the building of our portfolio.

MASC Trials membership continues to climb, with 138 new members since June 2019, bringing our membership network to 1,698 individuals across 35 countries, representing many of the major skin cancer treatment and research groups around the world.

MASC Trials has welcomed several new staff and now has a larger skilled workforce than ever before. The expansion of the team is mainly due to the securing of new research grants by our investigators and has been facilitated by establishment of the MASC Research Centre at the School of Public Health and Preventative Medicine at Monash University.

Recent Research Achievements:

- 204 patients enrolled / 13 protocols / 144 sites / 15 countries
- 17 new sites engaged (9 in AU, 8 international)
- Current active engagement across AU, NZ, UK, Ireland, USA, Canada, Scandinavia, Europe, Brazil
- 29 research grants submitted / 14 awarded (48%) / 4 outcomes awaited / 11 unsuccessful
- 18 new research ideas in development
- Reporting to 9 funding agencies / 15 (current) grants
- Reporting to Therapeutic Goods Administration for 4 current Clinical Trial Notification trials
- Responsible for 19 lead national ethical approvals

My thanks to the many past and current MASC Trials staff for their excellent work and support of our investigators and our growing research portfolio. MASC Trials affiliates have presented a number of important publications and presentations in Australia and abroad. For further details on our research achievements please see summary on page 53.

## CEO REPORT

MASC Trials has also hosted workshops, education sessions and patient education webinars throughout the year. We have also worked closely and strengthened engagement with the Australian Melanoma Consumer Alliance, the Melanoma Research Victoria Consumer Reference Group, and the AMIGOs and AOMA Patient Advocacy Groups. This has resulted in a number of successful grant applications in under-researched areas of need.

I am thankful for the tremendous opportunity and privilege to have worked alongside many passionate and dedicated colleagues in a role that I have greatly enjoyed. I recognise the wonderful collaborative spirit sustained across many years to support the expansion of the group, and would like to thank our members, advocates, directors, collaborators and funders – in particular Cancer Australia – for their commitment to the group's vision. To the clinical researchers and scientists, site staff, patients and families supporting MASC Trials, your efforts have been instrumental in improving patient outcomes.

Having served under three chairs over a decade, I would like to extend my sincere thanks and gratitude to Prof. Mark Shackleton for leading our transformation from ANZMTG to MASC Trials Ltd and for serving as founding Chair of the latter, to Prof. Bryan Burmeister for his steady hand in the key transitional years from 2014-7, and notably to Prof. Thompson, the founding Chair of ANZMTG in 1999.

MASC Trials has established a strong reputation as a leading organisation with a proven track record to create, conduct and deliver clinically relevant research, the results of which inform patient care and health policy world-wide.

Yours sincerely



**Ms Elizabeth Paton** BLAS, GAICD

Chief Executive, Melanoma and Skin Cancer Trials Limited  
Head of Operations, Melanoma and Skin Cancer  
Research Centre, Monash University



# 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 2020

	2020 \$
Revenue	241,755
<b>Total Revenue</b>	<b>241,755</b>
Event expenses	1,571
Registration and capitation fees	1,690
Statutory charges	448
<b>Total Expenses</b>	<b>3,709</b>

Statement of financial position as at 30 June 2020

### Assets

#### Current Assets

Cash and cash equivalents	254,046
<b>Total current assets</b>	<b>254,046</b>
<b>Total assets</b>	<b>254,046</b>

### Liabilities

#### Current Liabilities

Trade and other payables	5,000
Other liabilities	11,000
<b>Total liabilities</b>	<b>16,000</b>
<b>Net assets</b>	<b>16,000</b>

### Equity

Retained earnings	238,046
<b>Total equity</b>	<b>238,046</b>

The full Annual Financial Report and Director's Report, for the year ending 30 June 2020, audited by Charterpoint, are available at [www.acnc.gov.au/charity/](http://www.acnc.gov.au/charity/)

## PROJECTS

During the reporting period Melanoma and Skin Cancer Trials Ltd was responsible for management of the research and clinical activities presented in the table below. These studies are funded by competitive government grants or industry funding administered by universities, and are therefore not reported in the financial statements of Melanoma and Skin Cancer Trials Ltd (with the exception of 02.09 Mel-D Trial and 02.14 COMBI-RT Trial, where remaining funds were transferred to Melanoma and Skin Cancer Trials Ltd).

Protocol Title	Chief Investigator / Grant Holder	Lead administering institution
Support for Cancer Clinical Trials Scheme	Prof. Mark Shackleton	Monash University
Improving Melanoma and Skin Cancer awareness in regional and rural Australia	A/Prof. Victoria Mar	Monash University
AMIGOs activities	Prof. Mark Shackleton	Monash University
<b>07.17 Global Uveal Melanoma Registry</b> – AOMA Component	A/Prof. Anthony Joshua	Monash University
<b>01.07 WBRTMel Trial</b> – Whole Brain Radiotherapy following local treatment of intracranial metastases of melanoma – A randomised Phase III trial	Prof. Gerald Fogarty	Monash University
<b>01.09 RTN2 Trial</b> – A randomised trial of post-operative radiation therapy following wide excision of neurotropic melanoma of the head and neck	A/Prof. Matthew Foote	Metro South Health
<b>01.12 EAGLE FM Trial</b> – Evaluation of groin lymphadenectomy extent for metastatic melanoma – A randomised phase III trial to evaluate survival, morbidity, and quality of life	Prof. Andrew Spillane	Monash University
<b>01.15 CHARLI Trial</b> – 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	University of Melbourne
<b>02.09 Mel-D Trial</b> – Vitamin D following primary treatment of melanoma at high risk of recurrence – a pilot placebo controlled randomised Phase II trial	A/Prof. Robyn Saw	MASC Trials Limited
<b>02.12 RADICAL Trial</b> – A randomised controlled multicentre trial of imiquimod versus radiotherapy for lentigo maligna when staged surgical excision with 5mm margins is not possible, is refused, or fails	A/Prof. Pascale Guitera	University of Sydney

## PROJECTS

Protocol Title	Chief Investigator / Grant Holder	Lead administering institution
<b>02.14 Combi-RT Trial</b> – An open-label, single-arm, Phase I/II, multicentre study to evaluate the safety and efficacy of the combination of dabrafenib, trametinib and palliative radiotherapy in patients with unresectable (stage IIIc) and metastatic (stage IV) BRAF V600E/k mutation-positive cutaneous melanoma	Dr. Tim Wang	MASC Trials Limited
<b>02.18 MelMarT-II Trial</b> – A Phase III, multi-centre, multi-national randomised control trial investigating 1cm v 2cm wide excision margins for primary cutaneous melanoma	Prof. Michael Henderson	University of Melbourne
<b>02.19 IMAGE Trial</b> – Melanoma Surveillance Photography to improve early detection of melanoma in very high risk (or high risk) patients	A/Prof. Victoria Mar	Monash University
<b>3.12 MelMarT (Pilot) Trial</b> – A Phase III, multi-centre, multi-national randomised control trial investigating 1cm vs 2cm excision margins for primary cutaneous melanoma	Prof. Andrew Spillane	University of Sydney
<b>03.18 I-MAT Trial</b> – A randomised, placebo-controlled, Phase II trial of adjuvant Avelumab in patients with stage I-III Merkel cell carcinoma	Dr. Wen Xu	University of Queensland
<b>04.17 SMARTI Trial</b> – A Pilot Study of an Artificial Intelligence System as a Diagnostic Aide for Better Skin Cancer Management	A/Prof. Victoria Mar	Monash University
<b>10.17 GoTHAM Trial</b> – 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	University of Melbourne

## MASC TRIALS OVERVIEW

The MASC Trials Limited coordinates and conducts quality research for melanoma control with researchers and health care professionals, patients and support networks.

The role of MASC Trials is to support researchers to develop, conduct, complete and publish innovative, investigator-driven, melanoma and non melanoma skin cancer research which would be difficult for any single centre to deliver.

Currently, MASC Trials is funded entirely by competitive grants and therefore functions under strict grant terms. As part of these terms, MASC Trials cannot provide direct project funding and we do not act in the capacity of a funding agency. However, MASC Trials membership services includes providing support to researchers to apply for funding for protocols (which meet the endorsement criteria of the group).

The process for protocol endorsement is competitive and tethered to the limited capacity of the group and the members of the scientific advisory committee ranks concepts in respect to:



MASC Trials exists to serve our members to develop clinically relevant research. Services include but are not limited to the following:

- + Supporting development of clinical protocols and study documents
- + Assisting investigators in completing grant applications
- + Acting as a central point of contact and hub for researchers
- + Facilitating communication between melanoma services
- + Providing research education opportunities to members
- + Establishing quality assurance processes and standard operating procedures
- + Providing clinical trials expertise and advice

## MASC TRIALS WELCOMES NEW RESEARCH IDEAS!

In case you have any new concepts or want to know how we can help, please contact the team.

## BOARD OF DIRECTORS



**PROF. MARK SHACKLETON**  
MBBS PhD FRACP  
**CHAIR, MEDICAL ONCOLOGIST**



**PROF. ANDREW SPILLANE**  
MD FRACS BMBS BMedSci GAICD  
**DEPUTY CHAIR, SURGICAL ONCOLOGIST**



**PROF. GERALD FOGARTY**  
BSc MBBS(Hons) FRANZCR PhD  
**RADIATION ONCOLOGIST**



**A/PROF. VICTORIA MAR**  
MBBS PhD FACD  
**DERMATOLOGIST**



**MR RICHARD MARTIN**  
MBChB FRACS ChM(SurgOnc)  
**CUTANEOUS SURGICAL ONCOLOGIST**



**MR PAUL WHITE**  
FCA FGIA CIA GAICD  
**COMPANY SECRETARY, PATIENT ADVOCATE**



**PROF. MICHAEL MILLWARD**  
MBBS MA (Bioethics)  
**MEDICAL ONCOLOGIST**



**PROF H. PETER SOYER**  
MD FACD FAAHMS  
**DERMATOLOGIST**



**DR. DONNA MILNE**  
RN PhD  
**ADVANCED PRACTICE NURSE**

## MASC TRIALS TEAM



**LIBBY PATON**  
BLAS, GAICD  
**CEO / HEAD OF RESEARCH**



**NARELLE WILLIAMS**  
BAppSci(Nurs) MPH  
**NATIONAL RESEARCH MANAGER**



**JUNYA EGUCHI**  
BExPhys MS  
**CLINICAL DATA MANAGER**



**SAMANTHA MACNAMARA**  
BSc(Biochem) GC(AnSci) MClInRes  
**CLINICAL DATA MANAGER**



**ELIZABETH SADOWY**  
CertiVBusAdmin DipAcc  
**SENIOR OFFICE ADMINISTRATOR**



**DANIELA SEMINARA**  
MPharm  
**CLINICAL RESEARCH ASSOCIATE**



**MELISSA SHELDON**  
BComm  
**PROJECT OFFICER**



**VICTORIA STEEL**  
BSc  
**CLINICAL DATA MANAGER**



## STRATEGIC PLAN

MASC Trials are currently operating under the 2018-2023 Strategic Plan

# 2018 ————— 2023

**ENGAGE AND CONNECT** We will actively engage researchers, clinicians and patients with an interest in improving outcomes in melanoma and non-melanoma skin cancer and create a forum to share ideas and drive progress.

**FACILITATE RESEARCH EXCELLENCE** We will provide researchers with the infrastructure, tools, advice and support to conduct high-quality, clinically relevant, patient-centred research that has the potential to improve outcomes from melanoma and non-melanoma skin cancer.

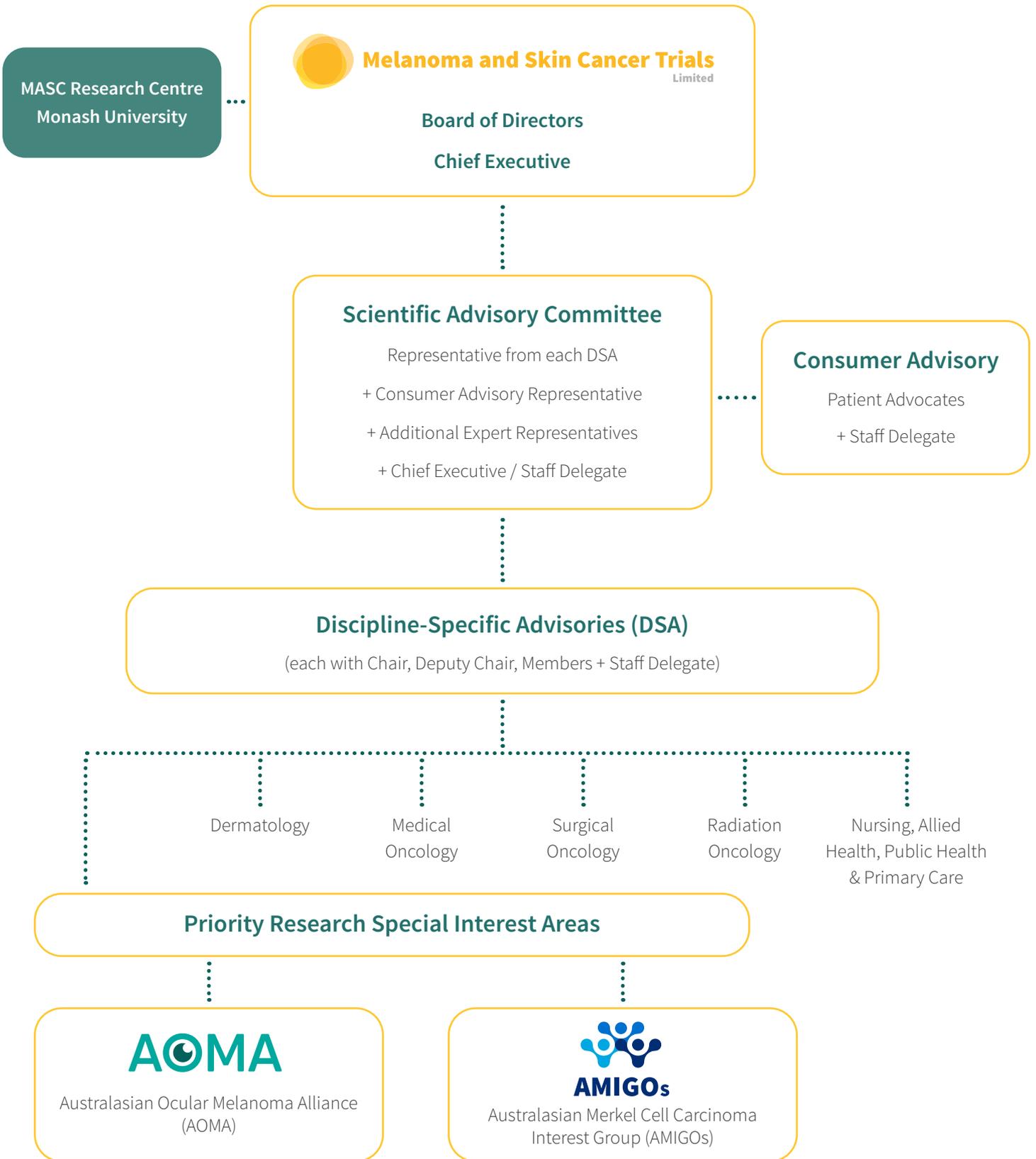
**INFORM AND IMPROVE** We will actively communicate with our membership and the broader health and research community to promote the benefits of high-quality investigator-driven research in melanoma and non-melanoma skin cancer and to encourage translation into practice.

**STRENGTHEN AND SUSTAIN** We will create robust and sustainable governance and organisational structures and processes to support the effectiveness and efficiency of our work and the research we support.

**LEARN AND EVOLVE** We will remain agile and responsive to changes in the health and research environment and to innovations in the diagnosis and treatment of melanoma and non-melanoma skin cancer to ensure that our activities remain relevant and create impact.

The MASC Trials Board continues to meet regularly across the year, as well as the Discipline Specific Advisory Committees, and Trial Operations meetings. Some delays have impacted on the Scientific Advisory Committee meetings which will resume in 2021. These meetings help to ensure our MASC Trials activities are aligned with our overarching Mission and Strategic Plan.

# ORGANISATIONAL STRUCTURE



## SCIENTIFIC ADVISORY COMMITTEE

### **PROF MARK SHACKLETON**

MASC Trials Chair

### **PROF ANDREW SPILLANE**

Nominated Representative,  
Surgical Oncology DSA

### **PROF DAVID WHITEMAN**

Chair, Nursing, Allied Health,  
Public Health & Primary  
Care DSA

### **DR DONNA MILNE**

Deputy Chair, Nursing,  
Allied Health, Public Health  
& Primary Care DSA

### **A/PROF MATTEO CARLINO**

Deputy Chair, Medical  
Oncology DSA

### **A/PROF ANTHONY JOSHUA**

Chair, Australian Ocular  
Melanoma Alliance (AOMA);  
Representative of the  
Medical Oncology DSA

### **PROF GERALD FOGARTY**

Chair, Australasian Merkel  
Cell Research Interest Group  
(AMIGOs); Representative of  
the Radiation Oncology DSA

### **A/PROF SHAHNEEN SANDHU**

Deputy Chair, Australasian  
Merkel Cell Research  
Interest Group (AMIGOs),  
Representative of the  
Medical Oncology DSA

### **A/PROF PASCALE GUITERA**

Co-Chair, Dermatology DSA

### **A/PROF HELMUT SCHAIDER**

Co-Chair, Dermatology DSA

### **DR ROSALIE STEPHENS**

Expert, New Zealand

### **PROF JON EMERY**

Expert, Chair-appointed  
SAC member

### **PROF RICHARD SCOLYER**

Expert, Chair-appointed  
SAC member

### **PROF GRAHAM MANN**

Expert, Chair-appointed  
SAC member

### **PROF MICHAEL MILLWARD**

Expert, Chair-appointed  
SAC member

### **DR SERIGNE LO**

Expert Statistician

### **MS ALISON BUTTON-SLOAN**

Expert, Patient Advocate

### **PROF MADELEINE KING**

Expert, Cancer Quality of  
Life (QoL) Representative

### **A/PROF RICHARD DE**

### **ABREU LOURENCO**

Expert, Health Economics  
Representative

### **ELIZABETH PATON**

Expert, MASC Trials

## PATIENT ADVOCACY AND CONSUMER ENGAGEMENT

MASC Trials values independent patient advocate and community feedback to ensure appropriate development of relevant research which meets the needs and objectives of the people most affected by these cancers.

MASC Trials acknowledges the role of the Australian Melanoma Consumer Alliance (AMCA) and current AMCA Chair, Mrs Alison Button Sloan, for their consistent and robust engagement which directly enhances the work that we undertake. MASC Trials looks forward to continuing this work with the Melanoma Research Victoria Consumer Reference Group.

MASC Trials recognise the important contribution of our national advocate representatives each of whom have made significant contributions to MASC Trials, AMIGOs and AOMA this year.



**MR PAUL WHITE**  
MASC TRIALS LIMITED,  
COMPANY SECRETARY



**MRS ALISON BUTTON-SLOAN**  
CHAIR, AUSTRALIAN MELANOMA CONSUMER ALLIANCE  
BOARD DIRECTOR, MELANOMA PATIENTS AUSTRALIA  
PATIENT ADVOCATE/REPRESENTATIVE – MASC TRIALS, COSA  
CLINICAL TRIALS CONSUMER NETWORK, CANCER COUNCIL VIC  
AND WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH



**PROF JONATHAN PINCUS**  
CHAIR, AUSTRALASIAN MERKEL CELL  
CARCINOMA INTEREST GROUP PATIENT  
ADVOCACY GROUP (AMIGOS PAG)



**MR WAYNE LIEBERMAN**  
AUSTRALASIAN MERKEL CELL CARCINOMA  
INTEREST GROUP PATIENT ADVOCACY GROUP  
(AMIGOS PAG)



**MS SUSAN VINE**  
FOUNDER, OCUMEL AUST AND NZ  
(OCULAR MELANOMA AUSTRALIA AND NEW ZEALAND)  
FACEBOOK GROUP AUSTRALIAN OCULAR MELANOMA  
ALLIANCE PATIENT ADVOCACY GROUP (AOMA PAG)



**AUSTRALIAN MELANOMA  
CONSUMER ALLIANCE**  
AMCA CONSISTS OF REPRESENTATIVES INCLUDING:  
MASC TRIALS, MELANOMA PATIENTS AUSTRALIA,  
MELANOMA INSTITUTE AUSTRALIA,  
AUSTRALIAN MELANOMA RESEARCH FOUNDATION,  
MELANOMA RESEARCH VICTORIA, MELANOMA WA  
AND MELANOMA TAS.



## MEMBERSHIP REPORT

Our membership has grown significantly since our organisation was founded. The membership represents all states, territories in Australia and New Zealand, as well as internationally. The members are dedicated to growing the research portfolio in treatment, surgery, radiation oncology, quality of life and survivorship.





## MEMBERSHIP REPORT

## RESEARCH PORTFOLIO

MASC Trials' portfolio covers a wide range of therapies, including targeted therapies and immunotherapy, and surgical, radiotherapy, exercise and prevention interventions. The program is further complemented by the wide variety of supporting research including translational research, health economic and patient reported outcomes impact. This year, several studies experienced delays in start up/screening/recruitment due to the COVID-19 pandemic.

Status	Protocol # and Acronym (CIA)	Total Number of Studies
Active Trials – Recruiting	01.10 CARPETS (Brown) 02.12 RADICAL (Guitera) 01.15 CHARLI (Sandhu) 04.17 SMARTI (Mar) 09.17 PRIME002 (Westhuizen) 02.18 MelMarT-II (Moncrieff/Henderson)	6
Active Trials – In Follow Up	01.07 WBRTMel (Fogarty) 01.09 RTN2 (Foote) 01.12 EAGLE FM (Spillane) 03.12 MelMarT Pilot (Moncrieff/Henderson) 01.14 ABC (Long) – Sponsored by MIA 02.14 CombiRT (Wang)	6
Active Trials – In Start Up	07.17 Uveal Melanoma Registry (Joshua) 10.17 GoTHAM (Sandhu) 03.18 I-MAT (Xu) 02.19 IMAGE (Mar)	4
New Research Proposals – Endorsed	04.19 / NRP26.18 SPECTRUM (Millward / Gray) 03.19 / NRP25.18 DREAMseq (Haydon) 01.19 / NRP10.18 DETECTION (Sandhu) 01.18 / NRP11.18 SUNBeAM (Sandhu)	4
New Research Proposals – In Development	NRP 01.18 (Bell)      NRP 13.18 (Carlino)      NRP 21.18 (Gedye) NRP 02.18 (Fogarty)      NRP 14.18 (Moseshvilli)      NRP 23.18 (AMIGOs) NRP 03.18 (Porceddu / Rischin)      NRP 15.18 (Joshua)      NRP 24.18 (Shepherd) NRP 05.18 (Cebon)      NRP 16.18 (AMIGOs)      NRP 27.18 (AMIGOs) NRP 06.18 (Siow)      NRP 17.18 (Shackleton / Gedye)      NRP 28.18 (AMIGOs) NRP 07.18 (Janda)      NRP 18.18 (Joshua) <b>+15</b> 2019 NRPs NRP 09.18 (Guitera)      NRP 20.18 <b>+4</b> 2020 NRPs NRP 12.18 (Joshua)      (Khosrotehrani)	41
Closed Trials	01.02 Adj. RT (Burmeister / Henderson) MSLTI (Thompson) – ANZ Support Only MSLTII (Thompson) – ANZ Support Only 01.07 SS01.13 Hair Spare (Fogarty) 01.09 MelQOL (Winstanley) 02.09 Mel-D (Saw) 01.13 Psycho-educational intervention RCT (Cust) 02.17 MEL-SELF Pilot (Bell) 03.17 Skin Cancer Prevention (Cust) 06.17 iMOVE (Milne) 04.18 / NRP 22.18 Surgical Management Survey (Gyorki / Subramaniam)	11

## CLINICAL TRIAL

MASC 01.07 The WBRTMel Trial

Whole Brain Radiotherapy following local treatment of intracranial metastases of melanoma – A phase III randomised trial

**Lead Group:**  
Melanoma and Skin  
Cancer Trials

**Sponsor:**  
Melanoma and Skin  
Cancer Trials

**Chief Investigator:**

Prof. Gerald Fogarty  
St Vincent's Hospital,  
Sydney, NSW



**Collaborative Groups / Partners:** Trans-Tasman Radiation Oncology Group (TROG)

**Lead Human Ethics Research Committee:** Royal Prince Alfred Hospital Human Research Ethics Committee

**Lead Academic Administering Institution:** Monash University

**Funding Agencies:** Cancer Australia and Cancer Research UK



215 patients recruited (total) | 220 patient recruitment (target)

32 active sites in 4 countries (Australia / Norway / UK / US)

\$AUD 1,531,000+ awarded

### Sites

Melanoma Institute Australia and  
Royal Prince Alfred Hospital  
St. Vincent's Hospital  
Westmead Hospital  
Nepean Hospital  
Royal North Shore Hospital  
Calvary Mater Hospital  
Genesis Cancer Care Newcastle

### Principal Investigator

Prof. Angela Hong  
Prof. Gerald Fogarty  
Dr. Tim Wang  
Dr. Tim Wang  
A/Prof. Michael Back  
Dr. Chris Wratten  
Dr. Michael Fay

### Location

Sydney, NSW, Australia  
Newcastle, NSW, Australia  
Newcastle, NSW, Australia

## Sites

Peter MacCallum Cancer Centre  
The Alfred Hospital  
Princess Alexandra Hospital  
Royal Brisbane and Women's Hospital  
Radiation Oncology Service –  
Mater Hospital Brisbane  
Townsville Hospital  
Genesis Cancer Care - Wesley  
Genesis Cancer Care - Chermside  
Genesis Cancer Care - Southport  
Genesis Cancer Care - Tugun  
Royal Adelaide Hospital  
NT Radiation Oncology  
Royal Hobart Hospital  
Sir Charles Gairdner Hospital  
The Radium Hospital  
Addenbrookes Hospital  
Charing Cross Hospital  
Churchill Hospital  
James Cook Hospital  
Mount Vernon Cancer Centre  
Norfolk and Norwich University Hospital  
St. James' University Hospital  
University Hospitals Dorset  
Velindre Hospital  
Penn State Hershey Cancer Centre

## Principal Investigator

Dr Kim Ung  
A/Prof. Jeremy Ruben  
Prof. Bryan Burmeister  
Dr. Roger Allison  
Dr. Andrew Pullar  
  
Dr. Sean Brennan  
Dr. Gail Tsang  
Dr. Art Kaminski  
Prof. David Christie  
Prof. David Christie  
Dr. Daniel Roos  
Dr. Saad Maqsood  
Dr. Raef Awad  
Dr. Sean Bydder  
Dr. Kari Dolven-Jacobsen  
Dr. Kate Fife  
Dr. Matthew Williams  
Prof. Mark Middleton  
Dr. Sarah Lawless  
Dr. Carie Corner  
Dr. Jenny Nobes  
Dr. Maria Marples  
Dr. Amitabha Chakrabarti  
Dr. Satish Kumar  
Dr. Rogerio Neves

## Location

Melbourne, VIC, Australia  
Melbourne, VIC, Australia  
Brisbane, QLD, Australia  
Brisbane, QLD, Australia  
Brisbane, QLD, Australia  
  
Townsville, QLD, Australia  
Brisbane, QLD, Australia  
Brisbane, QLD, Australia  
Gold Coast, QLD, Australia  
Gold Coast, QLD, Australia  
Adelaide, SA, Australia  
Darwin, NT, Australia  
Hobart, TAS, Australia  
Perth, WA, Australia  
Oslo, Norway  
Cambridge, United Kingdom  
London, United Kingdom  
Oxford, United Kingdom  
Middlesborough, United Kingdom  
London, United Kingdom  
Norwich, United Kingdom  
Leeds, United Kingdom  
Dorset, United Kingdom  
Cardiff, United Kingdom  
Pennsylvania, United States

# 2020 Achievements

Including important presentations  
and publications

The 01.07 WBRTMel trial results were published in the Journal of Clinical Oncology (DOI 10.1200 / JCO.19.01414) and presented at multiple conferences including ASCO, ASTRO and COSA, further publications have been drafted in 2020.

One manuscript has been published in the Applied Health Economics and Health Policy journal and three further publications are in draft.

Tran, G. B. Fogarty, A. K. Nowak, V. Diaby, A. Hong, C. Watts and R.L. Morton. Cost-Effectiveness of Subsequent Whole-Brain Radiotherapy or Hippocampal-Avoidant Whole-Brain Radiotherapy Versus Stereotactic Radiosurgery or Surgery Alone for Treatment of Melanoma Brain Metastases. Applied Health Economics and Health Policy, 11th March 2020, DOI: 10.1007/s40258-020-00560-1



### For more information

E: [wbrtmel@masc.org.au](mailto:wbrtmel@masc.org.au)

ANZCTR

ACTRN12607000512426

[Clinicaltrials.gov](https://clinicaltrials.gov)

NCT01503827

## CLINICAL TRIAL

MASC 01.07 SS01.13 The Hair Spare Study

**Lead Group:**  
Melanoma and Skin  
Cancer Trials

**Sponsor:**  
Melanoma and Skin  
Cancer Trials

**Chief Investigator:**  
Prof. Gerald Fogarty  
Genesis Cancer Care,  
Mater Hospital, Sydney, NSW



**Lead Human Ethics Research Committee:** Royal Prince Alfred Hospital Human Research Ethics Committee

**Lead Academic Administering Institution:** Monash University

**Funding Agency:** Cancer Australia



9 patients recruited (total) | 15 patient recruitment (target) | 1 active site in Australia

### Site

Genesis Cancer Care – Mater Hospital

### Principal Investigator

Prof. Gerald Fogarty

### Location

Sydney, NSW, Australia

## 2020 Achievements

Including important presentations  
and publications

The data for this study is currently being prepared for analysis and publication.



### For more information

E: [wbrtmel@masc.org.au](mailto:wbrtmel@masc.org.au)

ANZCTR

ACTRN1261700050738

## CLINICAL TRIAL

MASC 01.09 The RTN2 Trial

Randomised Trial of Post-Operative Radiation Therapy Following Wide Excision of Neurotropic Melanoma of the Head and Neck

**Lead Group:**  
Melanoma and Skin Cancer Trials

**Sponsor:**  
Melanoma and Skin Cancer Trials

### Chief Investigator:

A/Professor Matthew Foote  
Princess Alexandra Hospital,  
Brisbane, QLD



**Collaborative Groups / Partners:** Trans Tasman Radiation Oncology Group

**Lead Human Ethics Research Committee:** Metro South Health Service District Human Research Ethics Committee

**Lead Academic Administering Institution:** Princess Alexandra Hospital

**Funding Agency:** Cancer Australia



**3 patients recruited (2019/20) | 51 patients recruited (total) | 100 patient recruitment (target)**

**10 active sites in 4 countries** (Australia / Slovenia / UK / US)

**\$AUD 335,000 awarded**

### Sites

Princess Alexandra Hospital  
Calvary Mater Newcastle  
Melanoma Institute Australia  
MD Anderson Cancer Centre  
Memorial Sloan Kettering Cancer Centre

### Principal Investigator

A/Prof. Matthew Foote  
Dr. Mahesh Kumar  
Prof. Angela Hong  
Dr. Ashleigh Guadagnolo  
Dr. Christopher A. Barker

### Location

Brisbane, QLD, Australia  
Newcastle, NSW, Australia  
Sydney, NSW, Australia  
Texas, USA  
New York, USA

Sites	Principal Investigator	Location
Peter MacCallum Cancer Centre	Margaret Chua / Kathy Pope / Venessa Estall	Melbourne, VIC, Australia
Radiation Oncology Queensland Toowoomba	Dr. Sam Leung	Toowoomba, QLD, Australia
Radiation Oncology Services Mater Centre	Dr. Andrew Pullar	Brisbane, QLD, Australia
Royal Adelaide Hospital	Dr. Hui Tee	Adelaide, SA, Australia
Townsville Hospital	Dr. Alex Tan	Townsville, QLD, Australia
Westmead Hospital	Dr. Tim Wei Wang	Sydney, NSW, Australia
William Buckland Radiation Centre	A/Prof. Jeremy Ruben	Melbourne, VIC, Australia
Norfolk and Norwich University Hospital	Dr. Jenny Nobes	Norwich, UK
Institute of Oncology Ljubljana	Dr. Barbara Peric	Ljubljana, Slovenia
Sheffield Teaching Hospitals NHS Foundation Trust	Dr. James Lester	Sheffield, UK
Genesis Cancer Care – Tugun	David Christie / Art Kaminski / David Schlecht	Tugun, QLD, Australia
Genesis Cancer Care – Auchenflower	David Christie / Art Kaminski / David Schlecht	Brisbane, QLD, Australia
Genesis Cancer Care – Chermside	David Christie / Art Kaminski / David Schlecht	Brisbane, QLD, Australia
Genesis Cancer Care – Southport	David Christie / Art Kaminski / David Schlecht	Brisbane, QLD, Australia
Nottingham University Hospital NHS Trust	Dr. Pat Lawton	Nottingham, UK
University Hospital Southampton NHS Foundation Trust	Dr. Oliver Donnelly	Southampton, UK
Gosford Hospital	Dr. Joe Chang	Gosford, NSW, Australia

# 2020

## Achievements

Including important presentations and publications

The 01.09 RTN2 trial ceased recruitment on 25 February 2020, after recommendation from the Data Safety Monitoring Committee at a meeting held on 7 February 2020.

It was further recommended that there be a minimum of 12 months follow up of each patient and that following this, the primary endpoints, late toxicity and quality of life data be analysed and published.



**For more information**

E: [rtn2@masc.org.au](mailto:rtn2@masc.org.au)

ANZCTR  
ACTRN12610000478011

Clinicaltrials.gov  
NCT00975520

## CLINICAL TRIAL

MASC 02.09 The MEL-D Trial

Assessing the feasibility, safety and toxicity of vitamin D following primary treatment of melanoma at high risk of recurrence: A pilot placebo controlled randomised phase II trial

**Lead Group:**  
Melanoma and Skin  
Cancer Trials

**Sponsor:**  
Melanoma and Skin  
Cancer Trials

### Chief Investigator:

A/Prof. Robyn Saw  
Melanoma Institute Australia,  
Sydney, NSW



**Collaborative Groups / Partners:** Melanoma and Skin Cancer Trials

**Lead Human Ethics Research Committee:** Royal Prince Alfred Hospital Human Research Ethics Committee

**Lead Academic Administering Institution:** Melanoma Institute Australia

**Funding Agency:** Philanthropy



75 patients recruited (total) | 75 patient recruitment (target)

\$AUD147,000 awarded

### Sites

Melanoma Institute Australia /  
Royal Prince Alfred Hospital

### Principal Investigator

Dr. Robyn Saw

### Location

Sydney, NSW, Australia

## 2020 Achievements

Including important presentations  
and publications

Five year recurrence and survival data has now been analysed for the 02.09 Mel-D trial and a draft publication pertaining to the final data set is being prepared.



### For more information

E: [meld@masc.org.au](mailto:meld@masc.org.au)

ANZCTR

ACTRN12609000351213

## CLINICAL TRIAL

MASC 01.10 The CARPETS Trial

A phase I study of the safety and immune effects of an escalating dose of autologous GD2 chimeric antigen receptor-expressing peripheral blood T cells in patients with GD2-positive metastatic melanoma and refractory solid tumours

**Lead Group:**  
Royal Adelaide Hospital  
Cancer Centre

**Sponsor:**  
Royal Adelaide Hospital  
Cancer Centre

**Chief Investigator:**  
Prof. Michael Brown



**Collaborative Groups / Partners:** Melanoma and Skin Cancer Trials

**Lead Human Ethics Research Committee:** Royal Adelaide Hospital Human Research Ethics Committee

**Funding Agency:** National Health and Medical Research Council



2 patients recruited (2019/20) | 8 patients recruited (total) | 12 patient recruitment (target)

### Site

Royal Adelaide Hospital

### Principal Investigator

Prof. Michael Brown

### Location

Adelaide, SA, Australia



#### For more information

E: [Anne.milton@health.sa.gov.au](mailto:Anne.milton@health.sa.gov.au)

ANZCTR

ACTRN12613000198729

## CLINICAL TRIAL

MASC 01.12 The EAGLE FM Trial

Inguinal or Ilio-inguinal Lymphadenectomy for patients with metastatic melanoma to groin lymph nodes and no evidence of pelvic disease on PET/CT Scan – A randomised phase III trial

**Lead Group:**  
Melanoma and Skin  
Cancer Trials

**Sponsor:**  
Melanoma and Skin  
Cancer Trials

**Chief Investigator:**

Prof. Andrew Spillane  
Melanoma Institute Australia,  
Sydney, NSW



**Collaborative Groups / Partners:** Melanoma and Skin Cancer Trials

**Lead Human Ethics Research Committee:** Sydney Local Health District (Royal Prince Alfred Hospital)

**Funding Agencies:** Cancer Council NSW, The Friends of The Mater Foundation and Melanoma Institute Australia



**2 patients recruited (2019/20) | 101 patients recruited (total) | 634 patient recruitment (target)**

**15 hospitals across 6 countries** (Australia, UK, The Netherlands, Italy, Slovenia and Brazil)

**\$AUD 600,000 awarded**

### Sites

Melanoma Institute Australia /  
Royal Prince Alfred Hospital

Westmead Hospital

Mater Hospital

Peter MacCallum Cancer Centre

AC Camargo Cancer Centre

### Principal Investigator

Prof. Andrew Spillane /  
A/Prof. Robyn Saw

Prof. Julie Howle

Dr. Chris Allan

Prof. John Spillane

Dr. Joao Duprat

### Location

Sydney, NSW, Australia

Sydney, NSW, Australia

Brisbane, QLD, Australia

Melbourne, VIC, Australia

São Paulo, Brazil

## Sites

Hospital de Câncer de Barretos  
Norfolk and Norwich University Hospital  
Guy's and St Thomas's Hospitals NHS Trust  
St Helens and Knowsley NHS Trust  
St George Hospital  
Veneto Institute of Oncology  
Institute of Oncology Ljubljana  
University Medical Center Groningen  
Radboud University Medical Center

## Principal Investigator

Dr. Vinicius Vazquez  
Prof. Marc Moncrieff  
Mrs Jenny Geh  
Mr Rowan Pritchard-Jones  
Mr Barry Powell  
Dr. Marco Rastrelli  
Prof. Marko Hocevar  
Prof. Barbara Van Leeuwen  
Prof. Hans de Wilt

## Location

Barretos, Brazil  
Norwich, UK  
London, UK  
Rainhill, UK  
London, UK  
Padova, Italy  
Ljubljana, Slovenia  
Groningen, Netherlands  
Nijmegen, Netherlands

# 2020 Achievements

Including important presentations  
and publications

The 01.12 EAGLE FM Trial has officially ceased recruitment as of 4 November 2019 and patients are on active follow up. Patient follow up is ongoing and will be completed shortly. Data analysis and publication preparation will commence shortly.



### For more information

E: [eagle@masc.org.au](mailto:eagle@masc.org.au)

ANZCTR

ACTRN12614000721606

[Clinicaltrials.gov](https://clinicaltrials.gov)

NCT02166788

## CLINICAL TRIAL

MASC 02.12 The RADICAL Trial

A randomised controlled multicentre trial of imiquimod versus radiotherapy for lentigo maligna (LM) when staged surgical excision with 5mm margins is not possible, is refused, or fails

**Lead Group:**  
Melanoma and Skin  
Cancer Trials

**Sponsor:**  
Melanoma and Skin  
Cancer Trials

**Chief Investigator:**  
A/Prof. Pascale Guitera  
Melanoma Institute Australia,  
Sydney, NSW



**Collaborative Groups / Partners:** Melanoma and Skin Cancer Trials

**Lead Human Ethics Research Committee:** Sydney Local Health District (Royal Prince Alfred Hospital)

**Lead Academic Administering Institution:** University of Sydney

**Funding Agencies:** Cancer Australia via their PdCCRS scheme,  
Royal Australian and New Zealand College of  
Radiology and seed funding from Melanoma Institute Australia



**23 patients recruited (2019/20) | 118 patients recruited (total)**

**216 patient recruitment (target) | 10 active sites in 3 countries** (Australia, Brazil, New Zealand)

**\$AUD670,000 awarded**

Sites	Principal Investigator	Location
Royal Prince Alfred Hospital / Melanoma Institute Australia	A/Prof. Pascale Guitera	Sydney, NSW, Australia
Westmead Hospital	Prof. Pablo Fernández-Peñas	Sydney, NSW, Australia
Royal Adelaide Hospital	Dr. Andrew Potter	Adelaide, SA, Australia
Princess Alexandra Hospital	Prof. Peter Soyer	Brisbane, QLD, Australia
Calvary Mater Hospital Newcastle	Dr. Chris Wratten	Newcastle, NSW, Australia

## Sites

St Vincent's Hospital

Skin & Cancer Foundation Australia

North Shore Hospital

The Alfred Hospital

Hospital das Clinicas –  
Sao Paulo University

## Principal Investigator

Prof. Gerald Fogarty

Prof. Pablo Fernández-Peñas

Dr. Richard Martin

A/Prof. Victoria Mar

Dr. Lilian Rocha

## Location

Sydney, NSW, Australia

Sydney, NSW, Australia

Auckland, New Zealand

Melbourne, VIC, Australia

Sao Paulo, Brazil

# 2020 Achievements

Including important presentations  
and publications

“A practical guide on the use of Imiquimod cream for Lentigo Maligna” –  
P Guitera, A Waddell, E Paton, G B Fogarty, A Hong, R A Scolyer,  
J R Stretch, B A O'Donnell, G Pellacani – To be submitted to the Journal of  
European Academy of Dermatology and Venerology.

Robinson, M. et al., ‘Evidence-Based Clinical Practice Guidelines for the  
Management of Patients with Lentigo Maligna’, *Dermatology*. 2020;236(2):111-116.  
doi: 10.1159/000502470. Epub 2019 Oct 22. PMID: 316397882019

Menzies, S. et al., ‘Estimated risk of progression of lentigo maligna to lentigo  
maligna melanoma’, *Melanoma Res*. 2020 Apr;30(2):193-197. doi: 10.1097/  
CMR.0000000000000619. PMID: 31095041.

This year the RADICAL study team has applied to secure additional funding to  
expand the study. Results of the funding application are awaited.



### For more information

E: [radical@masc.org.au](mailto:radical@masc.org.au)

ANZCTR

ACTRN12615000266561

[Clinicaltrials.gov](https://clinicaltrials.gov)

NCT02394132

## CLINICAL TRIAL

MASC 03.12 The MelMarT Pilot Trial

Melanoma Margins Trial: A Phase III, multi-centre, multi-national randomised control trial investigating 1cm v 2cm wide excision margins for primary cutaneous melanoma.

**Lead Group:**  
Melanoma and Skin  
Cancer Trials

**Sponsor:**  
Melanoma and Skin  
Cancer Trials

**Chief Investigator:**

Prof. Marc Moncrieff  
(Study Chair)  
Norfolk and Norwich  
University Hospital (UK)



**Chief Investigator:**

Prof. Michael Henderson  
(Study Chair)  
Peter MacCallum  
Cancer Centre (AUS)



**Chief Investigator:**

Prof. Andrew Spillane  
(Lead Investigator)  
Melanoma Institute Australia /  
Royal Prince Alfred Hospital (AUS)



**Chief Investigator:**

A/Prof. David Gyorki  
(Lead Investigator)  
Peter MacCallum  
Cancer Centre (AUS)



**Chief Investigator:**

A/Prof. Robyn Saw  
(Lead Investigator)  
Melanoma Institute Australia /  
Royal Prince Alfred Hospital (AUS)



**Collaborative Groups / Partners:** Norfolk and Norwich University Hospital (NNUH)

**Lead Human Ethics Research Committee:** Sydney Local Health District (RPAH Zone)

**Lead Academic Administering Institution:** University of Sydney

**Funding Agencies:** Australian National Health and Medical Research Council (NHMRC)  
Cancer Australia  
Friends of the Mater Sydney





**400 patients recruited (total) | 400 patient recruitment (target)**

**20 active sites in 4 countries** (Australia, Sweden, UK, US) | **\$AUD 120,000**

Sites	Principal Investigator	Location
Peter MacCallum Cancer Centre	Prof. Michael Henderson	Melbourne, VIC, Australia
Melanoma Institute Australia / Royal Prince Alfred Hospital	Prof. Andrew Spillane / A/Prof. Robyn Saw	Sydney, NSW, Australia
The Alfred Hospital	Dr. Victoria Mar	Melbourne, VIC, Australia
Gold Coast Melanoma Clinic	Dr. Nic Crampton	Gold Coast, QLD, Australia
Sunnybrook Health Sciences Centre	Dr. Frances Wright	Ontario, Canada
Sahlgrenska University Hospital	Prof. Roger Olofsson Bagge	Gothenburg, Sweden
Thomas Jefferson University Hospital	Dr. Alliric Willis	Philadelphia, USA
Norfolk and Norwich University Hospital	Prof. Marc Moncrieff	Norwich, United Kingdom
St Helens and Knowsley NHS Trust	Mr Rowan Pritchard-Jones	Rainhill, England
Hull and East Yorkshire Hospitals NHS Trust	Mr Paolo Matteucci	Hull, England
North Bristol NHS Trust	Mr Ewan Wilson	Bristol, England
Mid Essex Hospital Services NHS Trust	Prof. Peter Dziejewski	Essex, England
Royal Free London NHS Trust	Mr Steven Hamilton	London, England
The Christie NHS Trust	Mr Deemesh Oudit	Manchester, England
Oxford University Hospitals NHS Trust	Mr Oliver Cassell	Oxford, England
Guy's and St Thomas's Hospitals NHS Trust	Mrs Jenny Geh	London, England
Imperial College Healthcare NHS Trust	Dr Navid Jallali	London, England
Cambridge University Hospitals NHS Trust (Addenbrooke's)	Mr Amer Durrani	Cambridge, England
Leeds Teaching Hospital NHS Trust	Mr Howard Peach	Leeds, England



**For more information**

E: [melmart@masc.org.au](mailto:melmart@masc.org.au)

ANZCTR

ACTRN12614000667617

| [Clinicaltrials.gov](https://Clinicaltrials.gov)

NCT02385214

## CLINICAL TRIAL

MASC 02.14 The COMBI-RT study

An open label, single-arm, phase/II, multicentre study to evaluate the safety and efficacy of the combination of dabrafenib, trametinib and palliative radiotherapy in patients with unresectable (stage IIIc) and metastatic (stage IV) BRAF V600E/K mutation-positive cutaneous melanoma

**Lead Group:**  
Melanoma and Skin  
Cancer Trials

**Sponsor:**  
Melanoma and Skin  
Cancer Trials

**Chief Investigator:**

Dr. Tim Wang  
Westmead Hospital,  
Sydney, NSW



**Lead Human Ethics Research Committee:** St Vincent's Hospital Sydney Human Research Ethics Committee

**Funding Agencies:** GlaxoSmithKline



**1 patient recruited (2019/20) | 10 patients recruited (total) | 30 patient recruitment (target)**

**9 active sites in Australia | \$AUD97,300 awarded**

### Sites

Princess Alexandra Hospital  
Westmead Hospital  
St Vincent's Hospital  
Liverpool Hospital  
Sydney Adventist Hospital  
Genesis Cancer Care – Auchenflower  
Genesis Cancer Care – Chermside  
Genesis Cancer Care – Southport  
Genesis Cancer Care – Tugun

### Principal Investigator

Dr. Mark Pinkham  
Dr. Tim Wang  
Prof. Gerald Fogarty  
Dr. Vanessa Estall  
Dr. Arthur Clements  
Dr. Art Kaminski  
Dr. Art Kaminski  
Prof. David Christie  
Prof. David Christie

### Location

Brisbane, QLD, Australia  
Sydney, NSW, Australia  
Sydney, NSW, Australia  
Sydney, NSW, Australia  
Sydney, NSW, Australia  
Brisbane, QLD, Australia  
Brisbane, QLD, Australia  
Gold Coast, QLD, Australia  
Gold Coast, QLD, Australia



# 2020

## Achievements

Including important presentations  
and publications

The 02.14 Combi-RT trial ceased recruitment on the 31st December 2019. Patient follow up has recently been completed. The data for this study is currently being prepared for analysis and publication.



### For more information

E: [combirt@masc.org.au](mailto:combirt@masc.org.au)

ANZCTR

[ACTRN12615000292572](https://www.anzctr.org.au/Trial/Registration/Trial.asp?id=12615000292572)

[Clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02392871)

[NCT02392871](https://clinicaltrials.gov/ct2/show/study/NCT02392871)

## CLINICAL TRIAL

MASC 01.15 The CHARLI Trial  
(CheckPoint And RANK-Ligand Inhibition)

A Phase Ib/II Trial of Ipilimumab-Nivolumab  
with Denosumab and Nivolumab with  
Denosumab in Patients with Unresectable  
Stage III and IV Melanoma

**Lead Group:**  
Peter MacCallum  
Cancer Centre

**Sponsor:**  
Peter MacCallum  
Cancer Centre

### Chief Investigator:

A/Prof. Shahneen Sandhu  
Medical Oncologist  
Melanoma Clinical & Trial Lead  
Peter MacCallum Cancer Centre,  
Melbourne, VIC



### Chief Investigator:

Prof. Grant McArthur  
Head Molecular Oncology Laboratory,  
Cancer Therapeutics Program and  
Consultant Medical Oncologist  
Senior Principal Research Fellow (NHMRC)  
Peter MacCallum Cancer Centre,  
Melbourne, VIC  
Chief Investigator  
Lorenzo Galli Chair in Melanoma  
and Skin Cancers, University of Melbourne, VIC



**Collaborative Groups / Partners:** Melanoma and Skin Cancer Trials

**Lead Human Ethics Research Committee:** Peter MacCallum Ethics Committee (16/153 HREC/16/PMCC/202)

**Funding Agencies:** Amgen: Funding for the entire study and drug supply (denosumab)

Bristol Myers Squibb: Drug supply (nivolumab and ipilimumab)

 Bristol Myers Squibb™





20 patients recruited (2019/20) | 32 patients recruited (total) | 72 patient recruitment (target)

8 active sites in Australia with 2 more sites in start-up

## Sites

Peter MacCallum Cancer Centre  
Royal Brisbane and Women's Hospital  
Box Hill Hospital  
Austin Health  
Bendigo Health  
Border Medical Oncology Research Unit  
Calvary Mater Newcastle  
Royal Hobart Hospital  
Alfred Health  
Sir Charles Gairdner Hospital

## Principal Investigator

A/Prof. Shahneen Sandhu  
Dr. Melissa Eastgate  
Dr. Andrew Mant  
Dr. Damien Kee  
Dr. Sam Harris  
Dr. Craig Underhill  
Dr. Craig Gedye  
Dr. Louise Knott  
Prof. Mark Shackleton  
Dr. Peter Lau

## Location

Melbourne, VIC, Australia  
Herston, QLD, Australia  
Box Hill, VIC, Australia  
Heidelberg, VIC, Australia  
Bendigo, VIC, Australia  
Albury, NSW, Australia  
Waratah, NSW, Australia  
Hobart, TAS, Australia  
Melbourne, VIC, Australia  
Nedlands, WA, Australia

# 2020 Achievements

Including important presentations  
and publications

Arm B of the 01.15 CHARLI trial underwent an interim safety analysis in June 2020. The Data Safety Monitoring Committee raised no concerns and it was recommended that both Arm A (nivolumab + denosumab) and Arm B (nivolumab + ipilimumab + denosumab) remain open to patient registrations and recruitment continue.



### For more information

E: [charli@masc.org.au](mailto:charli@masc.org.au)

ANZCTR

ANZCTR12617000772347

[Clinicaltrials.gov](https://clinicaltrials.gov)

NCT03161756

## CLINICAL TRIAL

### MASC 07.17 UVEAL MELANOMA REGISTRY

A Prospective Natural History Study in Uveal Melanoma

**Lead Group:**  
Columbia University

**Sponsor:**  
Melanoma and Skin  
Cancer Trials

**Chief Investigator:**  
A/Prof. Anthony Joshua  
St Vincent's Hospital



**Lead Human Ethics Research Committee:** St Vincent's Hospital Human Research Ethics Committee

**Lead Academic Administering Institution:** Monash University

**Funding Agencies:** Pulse Inframe, Bristol Myer Squibb



6 Australian sites are in start-up | \$USD 122,500 awarded

#### Sites

St Vincent's Hospital  
Chatswood Eye Specialists  
Private Rooms  
Royal Victorian Eye and Ear Hospital  
Royal Adelaide Hospital  
Perth Retina

#### Principal Investigator

A/Prof. Anthony Joshua  
Dr. Li-anne Lim  
A/Prof. Max Conway  
Prof. John McKenzie  
Dr. David Sia  
Dr. Tim Isaacs

#### Location

Sydney, New South Wales, Australia  
Sydney, New South Wales, Australia  
Sydney, New South Wales, Australia  
Melbourne, Victoria, Australia  
Adelaide, South Australia, Australia  
Perth, Western Australia, Australia

## CLINICAL TRIAL

MASC 04.17 The SMARTI Trial

Improving **S**kin Cancer **M**anagement  
with **ART**ificial Intelligence

**Lead Group:**  
Melanoma and Skin  
Cancer Trials

**Sponsor:**  
Monash University

### Chief Investigator:

Associate Professor Victoria Mar  
Adjunct Associate Professor  
NHMRC Early Career Research Fellow  
School of Public Health and Preventive Medicine  
Faculty of Medicine Nursing and Health Sciences  
Monash University  
Director, Victorian Melanoma Service  
Alfred Hospital



**Collaborative Groups / Partners:** MoleMap Pty Ltd

**Lead Human Ethics Research Committee:** Alfred Hospital Ethics Committee

**Lead Academic Administering Institution:** Monash University

**Funding Agencies:** Victoria Health – Department of Health and Human Services,  
Victorian Medical Research Acceleration Fund



**113 patients recruited (2019/20) | 113 patients recruited (total) | 220 patients recruited (target)**

**2 active sites in Australia | 1 site in start-up | \$AUD 100,000 awarded**

### Sites

Victorian Melanoma Service, Alfred Health  
Skin Health Institute

### Principal Investigator

A/Prof. Victoria Mar  
A/Prof. Peter Foley

### Location

Melbourne, VIC, Australia  
Carlton, VIC, Australia

## 2020 Achievements

Including important presentations  
and publications

Interim Quality Assurance Analysis results will  
be presented when available at the Victoria  
Melanoma Service Department Meeting.



### For more information

E: [smarti@masc.org.au](mailto:smarti@masc.org.au)

ANZCTR  
NCT04040114

Clinicaltrials.gov  
NCT04040114

## CLINICAL TRIAL

MASC 09.17 The PRIME-002 Trial

Early phase II study of Azacitidine and Carboplatin priming for Avelumab in patients with advanced melanoma who are resistant to immunotherapy

**Lead Group:**  
Calvary Mater  
Newcastle

**Sponsor:**  
Calvary Mater  
Newcastle

**Chief Investigator:**  
Dr. Andre Van der Westhuizen,  
Calvary Mater Newcastle,  
Newcastle, NSW



**Lead Human Ethics Research Committee:** Northern Sydney Local Health District HREC

**Lead Academic Administering Institution:** University of Newcastle

**Funding Agencies:** Cancer Institute NSW, Ramaciotti Foundation, Hunter Medical Research Institute, Maitland Cancer Appeal and Hunter Melanoma Foundation



10 patients recruited (2019/20) | 10 patients recruited (target) | 2 active sites in Australia

### Sites

Calvary Mater Newcastle  
Cairns Hospital

### Principal Investigator

Dr. Andre Van der Westhuizen  
Dr. Megan Lyle

### Location

Newcastle, NSW, Australia  
Cairns, QLD, Australia

## 2020 Achievements

Including important presentations  
and publications

In late 2019 interim analysis results were presented via poster at the Society for Melanoma Research Congress.



### For more information

E: [Nikola.bowden@newcastle.edu.au](mailto:Nikola.bowden@newcastle.edu.au)

ANZCTR

ACTRN12618000053224

## CLINICAL TRIAL

MASC 10.17 The GOTHAM Trial

A phase Ib/II study of combination avelumab with peptide receptor radionuclide therapy or conventional fractionated radiotherapy in patients with metastatic Merkel cell carcinoma

**Lead Group:**  
Melanoma and Skin  
Cancer Trials

**Sponsor:**  
Melanoma and Skin  
Cancer Trials

**Chief Investigator:**

A/Prof. Shahneen Sandhu,  
Peter MacCallum Cancer Centre,  
Melbourne, VIC



**Lead Human Ethics Research Committee:** Peter MacCallum Cancer Centre Human Research Ethics Committee

**Lead Academic Administering Institution:** Peter MacCallum Cancer Centre

**Funding Agencies:** Australian Government, Department of Health, Medical Research Futures Fund, Rare Cancers initiative and Merck Healthcare



65 patients recruitment (target) | 6 Australian sites in start-up  
\$AUD 2,400,000 awarded

### Sites

Peter MacCallum Cancer Centre  
Royal Brisbane and Women's Hospital  
Princess Alexandra Hospital  
Royal North Shore Hospital  
Royal Adelaide Hospital  
Sir Charles Gairdner Hospital

### Principal Investigator

Dr. Lavinia Spain  
A/Prof. David Wyld  
Dr. Wen Xu  
A/Prof. Alex Guminski  
Prof. Michael Brown  
Dr. Tarek Meniawy

### Location

Melbourne, Victoria, Australia  
Brisbane, Queensland, Australia  
Brisbane, Queensland, Australia  
Sydney, New South Wales, Australia  
Adelaide, South Australia, Australia  
Perth, Western Australia, Australia

# 2020 Achievements

Including important presentations  
and publications

## Presentations:

- *'Combination of Avelumab with Peptide Receptor Radionuclide Therapy (PRRT) or Conventional Fractionated Radiotherapy (RT) in Metastatic Merkel Cell Carcinoma (mMCC)'*; COSA's 46th Annual Scientific Meeting 2019, 12-14 November 2019, Adelaide, South Australia [Poster Presentation-Poster Session 1]
- Guminski A., *'A phase Ib/II study of combination avelumab with peptide receptor radionuclide therapy and conventional fractionated radiotherapy in patients with advanced Merkel cell carcinoma'*; International Symposium on Merkel Cell Carcinoma, 21-22 October 2019, Tampa, Florida, USA [Poster Presentation]



## CLINICAL TRIAL

MASC 02.18 The MelMarT-II Trial

Melanoma Margins Trial: A Phase III, multi-centre, multi-national randomised control trial investigating 1cm v 2cm wide excision margins for primary cutaneous melanoma

**Lead Group:**  
Melanoma and Skin  
Cancer Trials

**Sponsor:**  
Melanoma and Skin  
Cancer Trials

**Chief Investigator:**

Prof. Marc Moncrieff  
(Study Chair)  
Norfolk and Norwich  
University Hospital (UK)



**Chief Investigator:**

Prof. Michael Henderson  
(Study Chair)  
Peter MacCallum  
Cancer Centre (AUS)



**Chief Investigator:**

Prof. Andrew Spillane  
(Lead Investigator)  
Melanoma Institute Australia /  
Royal Prince Alfred Hospital (AUS)



**Chief Investigator:**

A/Prof. David Gyorki  
(Lead Investigator)  
Peter MacCallum  
Cancer Centre (AUS)



**Chief Investigator:**

A/Prof. Robyn Saw  
(Lead Investigator)  
Melanoma Institute Australia /  
Royal Prince Alfred Hospital (AUS)



**Collaborative Groups / Partners:** Norfolk and Norwich University Hospital and Canadian Cancer Trials Group

**Lead Human Ethics Research Committee:** Sydney Local Health District (RPAH Zone)

**Lead Academic Administering Institution:** University of Melbourne

**Funding Agencies:** Australian National Health and Medical Research Council

Canadian Institutes of Health Research

National Institute for Health Research Health Technology Assessment

National Cancer Institute





16 patients recruited (2019/20) | 16 patients recruited (total) | 2,998 patient recruitment (target)

3 active sites in 2 countries (Australia, Sweden) | 18 sites in start-up

\$AUD 2.77M + \$CAD 2.4M awarded

### Sites

Peter MacCallum Cancer Centre

Melanoma Institute Australia /  
Royal Prince Alfred Hospital

Sahlgrenska University Hospital

### Principal Investigator

Prof. Michael Henderson

Prof. Andrew Spillane /  
A/Prof. Robyn Saw

Prof. Roger Olofsson Bagge

### Location

Melbourne, VIC, Australia

Sydney, NSW, Australia

Gothenburg, Sweden

# 2020 Achievements

Including important presentations  
and publications

A number of new national and international hospital partnerships are in development.

On 5 June 2020, Dr Shirley Potter presented MelMarT-II Trial and Study Start Up information to Cancer Trials Ireland Disease Specific Sub Group (DSSG) in Ireland.



### For more information

E: [melmart@masc.org.au](mailto:melmart@masc.org.au)

[Clinicaltrials.gov](https://clinicaltrials.gov)

NCT03860883

## CLINICAL TRIAL

MASC 03.18 The I-MAT Trial

A randomised, placebo-controlled, phase II trial of adjuvant Avelumab in patients with stage I-III Merkel Cell Carcinoma

**Lead Group:**  
Melanoma and Skin  
Cancer Trials

**Sponsor:**  
Melanoma and Skin  
Cancer Trials

**Chief Investigator:**

Dr. Wen Xu



**Collaborative Groups / Partners:** Trans Tasman Radiation Oncology Group

**Lead Human Ethics Research Committee:** Metro South Human Research Ethics Committee

**Lead Academic Administering Institution:** University of Queensland

**Funding Agencies:** Australian Government, Department of Health, Medical Research Futures Fund, Rare Cancers initiative and Merck Healthcare



132 patient recruitment (target) | 12 Australian sites in start-up

\$AUD 3,400,000 awarded

### Sites

Alfred Health  
Townsville University Hospital  
Princess Alexandra Hospital  
Royal North Shore Hospital  
Royal Adelaide Hospital

### Principal Investigator

Prof. Mark Shackleton  
Dr. Madhavi Chilkuri  
A/Prof. Victoria Atkinson  
A/Prof. Alex Guminski  
Prof. Michael Brown

### Location

Melbourne, Victoria, Australia  
Brisbane, Queensland, Australia  
Brisbane, Queensland, Australia  
Sydney, New South Wales, Australia  
Adelaide, South Australia, Australia

Sites	Principal Investigator	Location
Peter MacCallum Cancer Centre	A/Prof. Shahneen Sandhu	Melbourne, Victoria, Australia
Calvary Mater Hospital	Dr. Ina Nordman	Sydney, New South Wales, Australia
Royal Brisbane and Women's Hospital	Dr. Melissa Eastgate	Brisbane, Queensland, Australia
Westmead Hospital	Prof. Michael Veness	Sydney, New South Wales, Australia
Chris O'Brien Lifehouse	Dr. Jenny Lee	Sydney, New South Wales, Australia
Melanoma Institute Australia	Prof. Georgina Long	Sydney, New South Wales, Australia
Affinity Oncology	A/Prof. Muhammad Adnan Khattak	Perth, Western Australia, Australia

## 2020 Achievements

Including important presentations and publications

### Publication

- Kok DL, Wang A, Xu W, Chua MST, Guminski A, Veness M, Howle J, Tothill R, Kichendasse G, Poulsen M, Sandhu S, Fogarty G. *The changing paradigm of managing Merkel cell carcinoma in Australia: An expert commentary.* Asia Pac J Clin Oncol. 2020 Aug 5. doi: 10.1111/ajco.13407. PMID: 32757453.



**For more information**  
E: [imat@masc.org.au](mailto:imat@masc.org.au)  
  
Clinicaltrials.gov  
NCT04291885

### Presentations

- Xu, W. et al., 'A randomised, placebo-controlled, phase II trial of adjuvant Avelumab in patients with stage I-III Merkel cell carcinoma (I-MAT Trial)', Australasian College of Dermatologists' Annual Scientific Meeting, 16-19 May 2020, Adelaide, South Australia [Poster Presentation]
- Pincus, J., on behalf of Lieberman, W., and Ruhle, C., 'The eviQ website advice on Merkel Cell Carcinoma treatment guidelines for Avelumab (ID 3463 v3) [letter to Cancer Institute NSW], 2 September 2019
- Fogarty, G., 'Meeting of the Minds: Merkel Cell Carcinoma Case Study Presentations', Dinner Symposium, 3 September 2019, Webinar streaming to Melbourne, Sydney, Brisbane [Oral Presentation]
- Fogarty, G., 'Improving the outlook for patients with Merkel cell carcinoma', International Symposium on Merkel Cell Carcinoma, 21-22 October 2019, Tampa, Florida, USA [Poster Presentation]
- Guminski, A., 'A randomised, placebo-controlled, phase II trial of adjuvant Avelumab in patients with early stage Merkel cell carcinoma', International Symposium on Merkel Cell Carcinoma, 21-22 October 2019, Tampa, Florida, USA [Poster Presentation]
- Xu, W., 'A randomised, double-blind, placebo-controlled, multi-institutional phase II study of adjuvant anti-PD-1 in patients with stage I-III Merkel cell carcinoma (I-MAT Study)', COSA's 46th Annual Scientific Meeting 2019, 12-14 November 2019, Adelaide, South Australia [Poster Presentation-Poster Session 1]
- Williams, N., 'Improving the outlook for patients with Merkel cell carcinoma', COSA 46th Annual Scientific Meeting, 12-14 November 2019, Adelaide, South Australia [Abstract Submission #316, Poster Presentation-Poster Session 2]
- Fogarty, G., Pincas, J., and Eguchi, J., 'Evolving Treatment Paradigms in Merkel Cell Carcinoma', Merck Pfizer and MASC Trials co-hosted AMIGOs Investigator Meeting, COSA 46th Annual Scientific Meeting, 12-14 November 2019, Adelaide, South Australia

## CLINICAL TRIAL

MASC 02.19 The IMAGE Trial

Melanoma surveillance photography to  
Improve early detection of Melanoma in  
ultra-high and high risk patients

**Lead Group:**  
Melanoma and Skin  
Cancer Trials

**Sponsor:**  
Monash University

### Chief Investigator:

A/Prof. Victoria Mar  
Adjunct Associate Professor

NHMRC Early Career Research Fellow  
School of Public Health and Preventive Medicine  
Faculty of Medicine Nursing and Health Sciences  
Monash University

Director, Victorian Melanoma Service  
Alfred Hospital



**Collaborative Groups / Partners:** The University of Sydney, The University of Queensland, The University of Queensland

**Lead Human Ethics Research Committee:** Alfred Hospital Ethics Committee

**Lead Academic Administering Institution:** Monash University

**Funding Agencies:** Australian Government – Department of Health: Medical Research Future Fund – Targeted Health System and Community Organisation Research competitive grant.



680 patient recruitment (target) | 9 sites in start-up | \$AUD 2,416,998 awarded

## Sites

Diamantina Institute –  
University of Queensland

Sunshine Coast University Hospital

Melanoma Institute Australia,  
Royal Prince Alfred Hospital

Westmead Hospital

Newcastle Skin Clinic

Victorian Melanoma Service, Alfred Health

Skin Health Institute

Bendigo Health

Bass Coast Health, Wonthaggi Hospital

## Principal Investigator

Prof. Peter Soyer

A/Prof. Helmut Schaidler  
Dr. Leith Banney

A/Prof. Pascale Guitera

Prof. Pablo Fernandez

Dr. Tony Azzi

A/Prof. Victoria Mar

A/Prof. Peter Foley

Dr. Samuel Harris

Dr. Renee Kelsall

## Location

Brisbane, QLD, Australia

Birtinya, QLD, Australia

Camperdown, NSW, Australia

Westmead, NSW, Australia

Newcastle, NSW, Australia

Melbourne, VIC, Australia

Carlton, VIC, Australia

Bendigo, VIC, Australia

Wonthaggi, VIC, Australia



### For more information

E: [image@masc.org.au](mailto:image@masc.org.au)

ANZCTR

NCT04385732

[Clinicaltrials.gov](https://clinicaltrials.gov)

NCT04385732

## MASC 05.19 RESEARCH PROJECT

Improving Melanoma and Skin Cancer awareness in regional and rural Australia

**Lead Group:**  
Melanoma and Skin  
Cancer Trials

**Sponsor:**  
Melanoma and Skin  
Cancer Trials

### Chief Investigator:

A/Prof. Victoria Mar  
MBBS PhD FACD  
Director, Victorian Melanoma Service, Alfred Hospital  
Adjunct Associate Professor  
NHMRC Early Career Research Fellow  
School of Public Health and Preventive Medicine  
Faculty of Medicine Nursing and Health Sciences  
Monash University



**Collaborative Groups / Partners:** Australian Melanoma Consumer Alliance  
Melanoma Patients Australia  
MelanomaWA  
Skin Cancer Tas (formally MelanomaTAS)  
Amie St Clair Foundation  
Melanoma Research Victoria  
Melanoma Institute Australia  
Cancer Research Economics Support Team  
Psycho-oncology Co-operative Research Group  
Primary Care Collaborative Cancer Clinical Trials Group  
Cancer Symptoms Trials  
Skin Health Institute  
Australasian Merkel Cell Carcinoma Interest Group  
Australasian Ocular Melanoma Alliance  
Rare Cancers Australia  
Skin Cancer College Australasia  
Cancer Council Australia  
The Royal Australian College of General Practitioners  
North Eastern Melbourne Integrated Cancer Service  
WA Kirkbride Melanoma Advisory Service  
Melanoma & Skin Cancer Advocacy Network  
Australian Melanoma Research Foundation  
Neuroendocrine Cancers Australia

**Lead Human Ethics Research Committee:** Monash University Human Research Ethics Committee

**Lead Academic Administering Institution:** Monash University

**Funding Agency:** Cancer Australia via the Supporting People with Cancer initiative



# 2020 Achievements

Including important presentations and publications

**For more information**  
E: [hello@masc.org.au](mailto:hello@masc.org.au)

Presentations:

Sheldon, M. and Milli, K., *'I am. I will'* Victorian Comprehensive Cancer Centre & University of Melbourne World Cancer Day event, 4 February 2020, Melbourne, Victoria [Oral Presentation]

Sheldon, M., *'Finding the X-Factor: Maximising the Impact of Immunotherapy'*, Victorian Comprehensive Cancer Centre (VCCC) Research Conference 2019, 16-17 September 2019, Melbourne, Victoria [Oral Presentation]

Sheldon, M., *'Living with metastatic melanoma'*, Victorian Comprehensive Cancer Centre (VCCC) Research Conference 2019, 16-17 September 2019, Melbourne, Victoria [Oral Presentation]



**“ I’m Emma, I’m 56 years old and I live on a farm about 50kms from the next major town. When I noticed a suspicious mark on my skin, I waited for a couple of weeks and then went to see my GP. He told me it was nothing & delayed my diagnosis for 1 year. ”**

**“ Then the bombshell was dropped, the facts and next steps were clear but I didn’t have any emotional support. How was I going to tell my family? ”**



## MASC TRIALS IN 2019/20

1,698+

group members  
representing

35 countries



144

institutions engaged  
in MASC Trials  
research



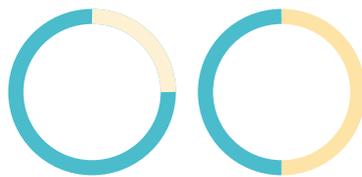
4,239+



trial participants  
have participated in  
MASC Trials studies  
since 1999

56

protocols; MASC Trials portfolio  
includes approximately 56 trials  
in various stages of recruitment,  
development, follow up, analysis  
and publication.



recruitment development



follow up



analysis



publication



MASC Trials research has been published in the top medical journals; the results of our research have informed Australian and international treatment guidelines for melanoma and skin cancer management.

## RESEARCH ACHIEVEMENTS

MASC Trials' research continues to change clinical practice on a global scale, demonstrating the leadership of our members in the melanoma and skin cancer research domain. We were delighted to share a number of presentations of new studies this year, as well as the publication of some of our long term follow up studies.

Protocol	Reference
01.07 WBRTMel	Tran, A. et al., 'Cost-Effectiveness of Subsequent Whole-Brain Radiotherapy or Hippocampal-Avoidant Whole-Brain Radiotherapy Versus Stereotactic Radiosurgery or Surgery Alone for Treatment of Melanoma Brain Metastases,' Applied Health Economics and Health Policy, 11th March 2020. DOI: 10.1007/s40258-020-00560-1. Epub ahead of print. PMID: 32157631
	Vardy, MD. et al., 'Neurocognitive outcomes from a phase 3 randomized trial comparing adjuvant whole brain radiotherapy with observation after local treatment of brain metastases in patients with melanoma,' 7th Biennial International Cognition and Cancer Task Force Meeting. 3-5 February 2020. Denver, Colorado. [Abstract]
	Tran, A. et al., 'Does Radiotherapy for Advanced Cancer Lead to Job Loss?,' Health Services Research Association Australia and New Zealand Conference, 4-6 December 2019, Auckland, New Zealand
	Fogarty, GB., 'A Phase 3 international trial of adjuvant whole brain radiotherapy (WBRT) or observation (Obs) following local treatment of 1-3 melanoma brain metastases (MBMs),' COSA's 46th Annual Scientific Meeting 2019, 12-14 November 2019, Adelaide, South Australia [Oral Presentation]
	Dhillon, H., 'Neurocognitive outcomes in a phase 3 randomised trial comparing adjuvant whole brain radiotherapy with observation after local treatment of brain metastases in patients with melanoma,' Clinical Oncology Society Australia's 46th Annual Scientific Meeting, 12-14 November 2019, Adelaide, South Australia, [oral presentation]
	Hong, A. et al., 'Adjuvant Whole-Brain Radiation Therapy Compared With Observation After Local Treatment of Melanoma Brain Metastases: A Multicenter, Randomized Phase III Trial,' Journal of Clinical Oncology, DOI: 10.1200/JCO.19.01414 Journal of Clinical Oncology 37, no. 33 (November 20, 2019) 3132-3141
	Fogarty, G. et al., 'Neurocognitive outcomes in a phase 3 randomized trial comparing adjuvant whole brain radiotherapy with observation after local treatment of brain metastases in patients with melanoma,' American Society for Radiation Oncology (ASTRO) meeting, 15-18 September 2019, Chicago, Illinois, USA [Abstract #33536 – Oral Presentation]
	Ternylia, D., 'Expert Highlights Key Studies Revolutionizing the Melanoma Treatment Landscape,' Targeted Oncology, <a href="https://www.targetedonc.com/view/expert-highlights-key-studies-revolutionizing-the-melanoma-treatment-landscape">https://www.targetedonc.com/view/expert-highlights-key-studies-revolutionizing-the-melanoma-treatment-landscape</a> (accessed 30 August 2019)
	Fogarty, G. et al., 'Phase 3 international trial of adjuvant whole brain radiotherapy (WBRT) or observation (Obs) following local treatment of 1-3 melanoma brain metastases (MBMs),' American Society for Radiation Oncology (ASTRO) meeting, 15-18 September 2019, Chicago, Illinois, USA [oral presentation]
	Bhatia S., 'Expert Highlights Key Studies Revolutionizing the Melanoma Treatment Landscape,' 2019 Best of ASCO Bellevue on Seattle's Eastside, 19-20 July 2019, Bellvue, Washington, USA [oral presentation]
	Hong, A., 'Adjuvant Whole-Brain RT Does Not Improve Outcomes in Melanoma Brain Mets,' American Society of Clinical Oncology (ASCO) meeting, 31 May-4 June 2019, Chicago Illinois USA. [Abstract #258029 – Late breaking Oral Presentation]
	Lo, S. et al., 'Whole brain radiotherapy (WBRT) after local treatment of brain metastases in melanoma patients: Statistical Analysis Plan.' Trials 20, 477 (2019) <a href="https://doi.org/10.1186/s13063-019-3555-5">https://doi.org/10.1186/s13063-019-3555-5</a>

Protocol	Reference
	Dhillon, H., 'Neurocognitive outcomes in a phase 3 randomised trial comparing adjuvant whole brain radiotherapy with observation after local treatment of brain metastases in patients with melanoma', COSA 46th Annual Scientific Meeting, 12-14 November 2019, Adelaide, South Australia [Oral Presentation]
01.09 RTN2	Williams, N., 'An International Randomised Trial of Post-operative Radiation Therapy Following Wide Excision of Neurotropic Melanoma of the Head and Neck', COSA 46th Annual Scientific Meeting, 12-14 November 2019, Adelaide, South Australia, [Abstract Submission #280, Poster Presentation]
	Foote, M. et al., 'A randomised trial of post operative radiation therapy following wide excision of neurotropic melanoma of the head and neck', COSA's 46th Annual Scientific Meeting 2019, 12 November 2019, Adelaide, South Australia [Poster Presentation-poster session 1]
02.12 RADICAL	Robinson, M. et al., 'Evidence-Based Clinical Practice Guidelines for the Management of Patients with Lentigo Maligna', <i>Dermatology</i> . 2020;236(2):111-116. doi: 10.1159/000502470. Epub 2019 Oct 22. PMID: 316397882019
	Menzies, S. et al., 'Estimated risk of progression of lentigo maligna to lentigo maligna melanoma', <i>Melanoma Res.</i> 2020 Apr;30(2):193-197. doi: 10.1097/CMR.0000000000000619. PMID: 31095041.
04.17 SMARTI	Mar V, SMARTI Update. presented at Melanoma Research and Therapy Special Interest Group Meeting, 27 November 2020, 12:00-12:45 AEST, virtual presentation [Oral Presentation]
	Mar,V., 'AI and skin cancer', Olivia Newton John Cancer Institute, 27 February 2020, Heidelberg, Victoria [Oral Presentation]
	Mar, V, 'Reconceiving early detection of melanoma', Melanoma Research Victoria Scientific Exchange, 3 December 2019, Melbourne, Victoria [Oral Presentation]
06.17 iMove	Hyatt, A. et al., 'i-Move, a personalised exercise intervention for patients with advanced melanoma receiving immunotherapy: a randomised feasibility trial protocol' <i>BMJ Open</i> 2020;10:e036059. doi: 10.1136/bmjopen-2019-036059
10.17 GoTHAM	'Combination of Avelumab with Peptide Receptor Radionuclide Therapy (PRRT) or Conventional Fractionated Radiotherapy (RT) in Metastatic Merkel Cell Carcinoma (mMCC)', COSA's 46th Annual Scientific Meeting 2019, 12-14 November 2019, Adelaide, South Australia [Poster Presentation-Poster Session 1]
02.18 MelMarT-II	Mammen, J., 'MelMarT Trial Information and Study Start Up', SWOG Group, October 2019, USA [Oral Presentation]
	Olofsson Bagge, R., 'MelMarT Trial Update', Congress of the European Society of Surgical Oncology (ESSO), 9-11 October 2019, Rotterdam, The Netherlands, [Oral Presentation]
	Moncrieff, M., 'Melanoma Margins Trial (MelMarT) A Phase III, multi-centre, multi-national randomised control trial investigating 1cm v 2cm wide excision margins for primary cutaneous melanoma, 03.12 MelMarT Pilot, 02.18 MelMarT-II', European Organisation for Research and Treatment of Cancer (EORTC), 12 October 2019 [Oral Presentation]
	Roger Olofsson Bagge, MelMarT Trial Update, Swedish Surgical Society Surgical Week, 9:20-9:40-Melanoma Surgery, 20th August 2019 [Oral Presentation]
03.18 i-MAT	Xu, W. et al., 'A randomised, placebo-controlled, phase II trial of adjuvant Avelumab in patients with stage I-III Merkel cell carcinoma (I-MAT Trial)', Australasian College of Dermatologists' Annual Scientific Meeting, 16-19 May 2020, Adelaide, South Australia [Poster Presentation]

## RESEARCH ACHIEVEMENTS

Protocol	Reference
	Xu, W., 'A randomised, double-blind, placebo-controlled, multi-institutional phase II study of adjuvant anti-PD-1 in patients with stage I-III Merkel cell carcinoma (I-MAT Study); COSA's 46th Annual Scientific Meeting 2019, 12-14 November 2019, Adelaide, South Australia [Poster Presentation-Poster Session 1]
04.18 Surgical Management Survey	Downs, JS., et al. 'A Survey of Management of the Sentinel Node Positive Melanoma Patient in the post-MSLT2 Era (manuscript accepted for publication) November 2020.
Australasian Merkel Cell Carcinoma Interest Group (AMIGOs)	Williams, N., 'Improving the outlook for patients with Merkel cell carcinoma', COSA 46th Annual Scientific Meeting, 12-14 November 2019, Adelaide, South Australia [Abstract Submission #316, Poster Presentation-Poster Session 2]
	Fogarty, G., 'Improving the outlook for patients with Merkel cell carcinoma', International Symposium on Merkel Cell Carcinoma, 21-22 October 2019, Tampa, Florida, USA [Poster Presentation]
	Fogarty, G., 'Punching above its weight', International Symposium on Merkel Cell Carcinoma, 21-22 October 2019, Tampa, Florida, USA [Poster Presentation]
	Blenkiron, C., 'A Spatial Proteomics Approach to Understanding the Immune Microenvironment in virus negative Merkel Cell Carcinomas', International Symposium on Merkel Cell Carcinoma, 21-22 October 2019, Tampa, Florida, USA [Poster Presentation]
	Blenkiron, C., 'Merkel Cell Polyoma Virus is uncommon in New Zealand Merkel Cell Carcinomas and associates with clinical features', International Symposium on Merkel Cell Carcinoma, , 21-22 October 2019, Tampa, Florida, USA [Poster Presentation]
	De Ieso, P., 'Clinical implications of Merkel cell polyomavirus status in patients with Merkel cell carcinoma at the Peter MacCallum Cancer Centre', International Symposium on Merkel Cell Carcinoma, 21-22 October 2019, Tampa, Florida, USA [Poster Presentation]
	Howle, J., 'Outcome for node positive Merkel cell carcinoma patients is similar irrespective of treatment delivered or nodal extent: The Westmead hospital experience', International Symposium on Merkel Cell Carcinoma, 21-22 October 2019, Tampa, Florida, USA [Poster Presentation]
	Kok, D., 'Merkel cell carcinoma: 38 year experience at the Peter MacCallum Cancer Centre', International Symposium on Merkel Cell Carcinoma, 21-22 October 2019, Tampa, Florida, USA [Poster Presentation]
	Tothill, R., 'Exploring gamma delta T cells in Merkel cell carcinoma', International Symposium on Merkel Cell Carcinoma, 21-22 October 2019, Tampa, Florida, USA [Poster Presentation]
	Fogarty, G., 'Meeting of the Minds: Merkel Cell Carcinoma Case Study Presentations', Dinner Symposium, 3 September 2019, Webinar streaming to Melbourne, Sydney, Brisbane [Oral Presentation]
	Pincus, J., on behalf of Lieberman, W., and Ruhle, C., 'The eviQ website advice on Merkel Cell Carcinoma treatment guidelines for Avelumab' (ID 3463 v3) [letter to Cancer Institute NSW], 2 September 2019
	Kok, DL. et al., 'The Changing Paradigm of Managing Merkel Cell Carcinoma in Australia: An Expert Commentary', Asia Pacific Journal of Clinical Oncology. 2020;1-8. <a href="https://doi.org.10.1111/ajco.13407">https://doi.org.10.1111/ajco.13407</a>
	Fogarty, G., Pinncais, J., and Eguchi, J., 'Evolving Treatment Paradigms in Merkel Cell Carcinoma', Merck Pfizer and MASC Trials co-hosted investigator meeting, COSA 46th Annual Scientific Meeting, 12-14 November 2019, Adelaide, South Australia

Protocol	Reference
Improving melanoma and skin cancer outcomes for people living in rural and regional Australia	Mar, V., ' <i>Melanoma diagnosis and staging</i> ' MASC Trials-Virtual Presentation, 16 April 2020, Melbourne, Victoria [Oral Presentation]
	Fogarty, G., ' <i>Radiotherapy in Cancer treatment</i> ', MASC Trials-Virtual Presentation, 6 April 2020, Melbourne, Victoria [Oral Presentation]
	Sheldon, M. and Milli, K., ' <i>I am. I will</i> ' Victorian Comprehensive Cancer Centre & University of Melbourne World Cancer Day event, 4 February 2020, Melbourne, Victoria [Oral Presentation]
	Mackley, J., Britto, J., Athan, S., and Leckie, L., ' <i>Build it together or fail alone; Best practice consumer engagement is an important area of focus for the VCC</i> ', Victorian Comprehensive Cancer Centre Consumer Focused Webinar, 9 December 2019, Australia [Oral Presentation]
	Sheldon, M., and McArthur, G., ' <i>Designer Drugs for Clinical Trials in Oncology</i> ', University of Melbourne, 8 October 2019, Melbourne, Victoria [Oral Presentation]
	Sheldon, M., ' <i>Finding the X-Factor: Maximising the Impact of Immunotherapy</i> ', Victorian Comprehensive Cancer Centre (VCCC) Research Conference 2019, 16-17 September 2019, Melbourne, Victoria [Oral Presentation]
	Sheldon, M., ' <i>Living with metastatic melanoma</i> ', Victorian Comprehensive Cancer Centre (VCCC) Research Conference 2019, 16-17 September 2019, Melbourne, Victoria [Oral Presentation]

## ACKNOWLEDGEMENTS

MASC Trials recognises and thanks our many supporters, their support has ensured our research makes a real difference to the treatment and outcomes of people affected by melanoma and skin cancers.

- Patients and their loved ones for participating in MASC Trials research
- Chief investigators and their research teams
- Hospital site staff including but not limited to principal and co-investigators, nursing, trials staff, data managers, administration, pathology, pharmacy and imaging staff
- Growing MASC membership now representing 35 countries
- Academic collaborators across Australia and around the world
- Fantastic network of MASC Trials, AMIGOs and AOMA patient advocates
- MASC Trials board of directors
- MASC Trials staff and management
- National Technical Services and expertise
- Monash University
- Various other Australian universities with whom we collaborate to successfully deliver multi-institutional research
- Members of the national Human Research Ethics Committees and Research Governance Officers across Australia and internationally
- Australian funding agencies and institutions including:
  - Cancer Australia
  - National Health and Medical Research Council
  - Medical Research Futures Fund
  - Cancer Council Australia
  - Friends of the Mater Research Foundation
  - ANZ College of Radiology
  - Melanoma Institute Australia
  - Cancer Council NSW
- Various international funding agencies and institutions across NZ, the UK, Ireland, Europe, Scandinavia, Canada, USA and Brazil
- Industry partners including:
  - Merck
  - Pfizer
  - Sanofi
  - Amgen
  - Novartis
  - Immunocore
  - Pulse Infocore
  - Bayer
  - Inservio
  - Lumos Medical
  - Bausch and Lomb
  - Johnson and Johnson Vision

