AUSTRALIAN CANCER RESEARCH FOUNDATION

ACRF AUSTRALIAN CENTRE OF EXCELLENCE IN

Melanoma Imaging and Diagnosis

HIGHLIGHTS OF THE 2023 ANNUAL REPORT

Finalised on 23rd February 2023

The University Of Queensland AUSTRALIA

The University of Sydney

Monash University

Executive Summary

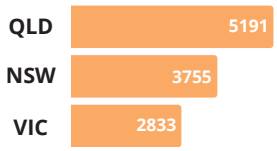
ACRF AUSTRALIAN CENTRE OF EXCELLENCE IN

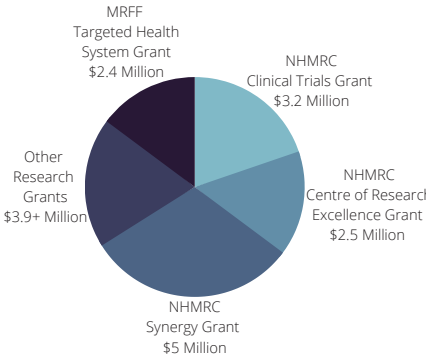
Melanoma Imaging & Diagnosis

Vision: A World Without Melanoma
Purpose: Establish a network of 3D total body imaging systems to improve early diagnosis and surveillance of melanoma

11,500+ Expressions of Interest

To enrol in our clinical trials from across Australia.





$17 Million+ in Research Funding

Leveraged across ACRF ACEMID partners.

ACRF ACEMID is conducting the WORLD's largest melanoma imaging study

Providing the foundation for 3D total body imaging within a telemedicine network and advancing melanoma research.

ACRF ACEMID Recruitment

We aim to recruit **15,000** participants, **1,000** participants at each site.

QLD Enrolments

Almost 1400 people have been enrolled into 2 Brisbane sites: Princess Alexandra Hospital and the Herston Imaging Research Facility.

NSW Enrolments

Over 1000 people have been enrolled into the Melanoma Institute Australia and the Westmead Hospital in Sydney.

VIC Enrolments

300 people have been enrolled at 3 sites: Alfred Hospital, Skin Health Institute and Bendigo Health.

Since 2021, ACRF ACEMID have established 11 sites across Australia.

Sept 2021 ACEMID Launch

- **Feb 2021** Princess Alexandra Hospital Brisbane (QLD)
- **May 2021** Melanoma Institute Australia Sydney (NSW)
- **May 2021** Alfred Hospital Melbourne (VIC)
- **June 2021** Westmead Hospital Sydney (NSW)
- **Aug 2021** Skin Health Institute Melbourne (VIC)
- **Jan 2022** Cairns Hospital Cairns (QLD)
- **Feb 2022** Herston Imaging Research Facility Brisbane (QLD)
- **July 2022** Bendigo Health (VIC)
- **Sept 2022** Bass Coast (VIC)
- **Oct 2022** Peter MacCallum Cancer Centre (VIC)
- **Feb 2023** Sunshine Coast University Hospital (QLD)

ACRF ACEMID plans to **expand to 15 sites.**

THE ACRF ACEMID PROJECT

The vision of the **ACRF Australian Centre of Excellence in Melanoma Imaging and Diagnosis** (ACRF ACEMID) is a "World Without Melanoma". To achieve this vision, ACRF ACEMID will deliver a next-generation, precision strategy of skin imaging technology integrated within a telemedicine network spanning 15 dermatology research nodes across Queensland, New South Wales, and Victoria to reconceive how melanoma is screened and detected. ACRF ACEMID will:

- Establish a network of state-of-the-art 3D total body imaging systems and informatics infrastructure to form a multidisciplinary and multi-site centre of excellence; the first of its kind internationally.
- Integrate and leverage world-class research expertise that is unique to Australia to provide technologically disruptive and reliable solutions for the early diagnosis of melanoma, particularly for people at high and ultra-high risk and spanning urban and regional/rural areas.
- Champion a reduction in the overarching burden, morbidity and mortality associated with the 17,000 invasive melanomas occurring yearly in Australia by helping ensure that healthcare services are targeted effectively and equitably to Australians most in need. Channelling people into risk stratified screening or surveillance programs will enable significant personal and health care system cost-savings.

The ACRF ACEMID lead researchers are Prof H. Peter Soyer (QLD), Prof Pablo Fernandez-Peñas (NSW) and A/Prof Victoria Mar (VIC). The core research team, in combination with an exceptionally strong, multidisciplinary team of additional researchers, and alongside senior health, informatics, and hospital staff, enable the successful implementation of ACRF ACEMID.

ESTABLISHMENT OF ACRF ACEMID SITES

As of February 2023, there are 11 ACRF ACEMID sites established.

Six sites were established during 2022 and early 2023.

- **Sunshine Coast University Hospital, QLD** – installed in February 2023. Cohort Study recruitment is anticipated to commence in April 2023.
- **Peter MacCallum Cancer Centre, Melbourne, VIC** – installed in October 2022. Cohort Study recruitment is anticipated to commence in Q2 2023.
- **Wonthaggi Hospital, Bass Coast Health, VIC** – installed in September 2022. Cohort Study recruitment is anticipated to commence in Q2 2023.
- **Bendigo Hospital, VIC** – installed in July 2022. Cohort Study recruitment commenced in November 2022 with 52 participants enrolled.
- **Herston Imaging Research Facility, Brisbane, QLD** – installed in February 2022. Cohort Study recruitment commenced in August 2022 with 575 participants enrolled.
- **Cairns Hospital, QLD** – installed in January 2022. Cohort Study recruitment in anticipated to commence in March 2023.

This adds to the five ACRF ACEMID sites established in 2021.

- **Skin Health Institute, Melbourne, VIC** – installed in August 2021. Cohort Study recruitment commenced in April 2022 with 108 participants enrolled. IMAGE Trial recruitment commenced in October 2021 with 60 participants enrolled, of which 29 are undergoing 3D total body imaging.
- Westmead Hospital, Sydney, NSW – installed in June 2021, relocated in May 2022. Cohort Study recruitment commenced in July 2022 with 262 participants enrolled. IMAGE Trial recruitment commenced in September 2022 with 12 participants enrolled, of which 7 are undergoing 3D total body imaging.

Westmead Go-Live photo (July 2022)

- **Melanoma Institute Australia, Sydney, NSW** – installed in May 2021. Cohort Study recruitment commenced in August 2021 with 744 participants enrolled.
- **The Alfred Hospital, Melbourne, VIC** – installed in May 2021. Cohort Study recruitment commenced in September 2022 with 140 participants enrolled. IMAGE Trial recruitment commenced in March 2021 with 126 participants enrolled, of which 47 are undergoing 3D total body imaging.
- **Princess Alexandra Hospital, Brisbane, QLD** – previously established. Cohort Study recruitment commenced in February 2021 with 824 participants enrolled. IMAGE Trial recruitment commenced in February 2021 with 75 participants enrolled, of which 39 undergoing 3D total body imaging.

There are four ACRF ACEMID sites to be established in NSW and QLD during 2023. Installation is anticipated to occur in Q2 2023 at Mt Isa, QLD; Port Macquarie, NSW; Wagga Wagga, NSW; and another NSW location, yet to be determined.

ACRF ACEMID COHORT STUDY

The Cohort Study has enrolled 2706 participants to date at the seven active ACRF ACEMID sites.

The ACRF ACEMID Cohort Study is the core study utilising the ACRF funded 3D total body imaging systems for the monitoring of skin lesions and the early detection of melanoma and other skin cancers.

It will enrol up to 15,000 adult participants across the 15 ACRF ACEMID sites in QLD, NSW, and VIC.

Study participants are placed into 3 groups based on their calculated risk of melanoma with study visits occurring 6 monthly for the very high-risk group, 12 monthly for the high-risk group, and 24 monthly for the low/average risk group.

The Cohort Study collects a range of data including total body and linked dermoscopy images, questionnaire data (including demographics, behavioural, quality of life, personal and family history), and clinical data. Approval has also been obtained to access Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Schedule (PBS) data.

Over the last 12 months pathology data collection, including scanning of histopathology slides of participant's biopsied lesions, has commenced. Saliva sample collection, for future genetic analyses, has also commenced at the central metropolitan sites in each state.

The Cohort Study obtained ethical approval by the Metro South Human Research Ethics Committee (Approval number: HREC/2019/QMS/57206) and The University of Queensland (Approval number: 2019003077). The trial is registered on the Australian New Zealand Clinical Trials Registry (ANZCTR12619001706167).

The ACRF ACEMID Cohort Study is funded by a NHMRC Clinical Trials and Cohort Studies Grant (APP2001517). This funding contributes to supporting the research personnel and many activities associated with conducting the ACEMID Cohort Study.

IMAGE TRIAL

The IMAGE Trial officially launched in February 2021 and has 10 sites open for recruitment across metro and regional Queensland, Victoria, and New South Wales, utilising the ACRF ACEMID 3D total body imaging systems where available and 2D total body photography (TBP) otherwise.

630 participants have joined the IMAGE trial to date, with 122 undergoing 3D total body imaging at four ACRF ACEMID sites (Alfred Hospital, Princess Alexandra Hospital, Skin Health Institute, Westmead Hospital).

Whilst Melanoma Surveillance Photography (MSP) is recommended in the Australian melanoma clinical practice guidelines for surveillance of high-risk individuals, the Medical Services Advisory Committee (MSAC) identified several gaps in the evidence which require addressing before an informed recommendation about Medicare Benefits Schedule listing of MSP can be made.

The IMAGE Trial will address these evidence gaps and determine the extent to which MSP, comprised of 2D and 3D TBP plus digital dermoscopy, improves diagnostic performance for melanoma and reduces the number of unnecessary biopsies during the surveillance of high- and very high-risk individuals.

The IMAGE Trial is funded by an MRFF Targeted Health System and Community Organisation Research Grant – Melanoma Surveillance Photography to improve early detection of melanoma in very high risk (or high risk) patients (APP1175082).

CRE IN SKIN IMAGING & PRECISION DIAGNOSIS

This CRE is focused on enhancing melanoma early detection and diagnosis through improved diagnostic processes and procedures, consists of six work programs, and will use data generated by the ACEMID Cohort Study.

CRE Programs 1 & 2 aim to develop and improve artificial intelligence (AI) algorithms, such as naevus, freckling and sun damage scores. As part of these programs an AI Researcher meeting was held in April 2022, followed by AI Workshops in June 2022 and February 2023.

CRE Program 3 will investigate the scarless biopsy method (also called tape stripping) with development of the study protocol and ethics application commencing in late 2022.

CRE Program 4 centres on integrating personalised home-based digital imaging support as part of the melanoma surveillance pathway. The ACRF ACEMID Consumer & Community Engagement Working Group are contributing to this program and a systematic review on the use of apps for skin self-examination has commenced.

CRE Program 5 aims to assess what study designs and validation methods are needed for health technology assessment of AI and omics driven diagnostics. A literature review is underway along with an ethics application to interview health technology assessors.

CRE Program 6 looks at the framework for ethical, legal, and social governance, particularly for privacy and confidentiality in dermatology imaging. Initial work has included a Consumer Forum on this topic in March 2022 and a resultant publication in the Australasian Journal of Dermatology in November 2022.

An overview of the CRE in Skin Imaging & Precision Diagnosis can be found on the ACRF ACEMID project website.

The CRE project is funded by a NHMRC Centre of Research Excellence Grant (APP2006551).

ROADMAP OPTIONS FOR MELANOMA SCREENING IN AUSTRALIA

This project aims to co-design, with consumers and healthcare stakeholders, a precision targeted melanoma screening approach to inform clinical and policy recommendations for an effective national risk-stratified melanoma screening program.

It will provide a blueprint for a nationwide policy strategy for effective skin screening and surveillance, by evaluating risk stratification and who needs targeted skin screening, and investigating stakeholder trust, both by consumers and clinicians.

Initial work has resulted in a publication of results from a survey about consumer acceptance of 3D total body imaging in the International Journal of Dermatology (2023). And a Consumer Forum was held in November 2022 on 'The future of melanoma screening' to facilitate discussions around our vision for a targeted melanoma screening program and new technologies that could be incorporated in melanoma screening and surveillance in the future.

An overview of the Roadmap Options for Melanoma Screening in Australia project can be found on the ACRF ACEMID project website.

The Roadmap Options for Melanoma Screening in Australia project is funded by a NHMRC Synergy Grant (APP2009923).

CONSUMER ENGAGEMENT FOCUS

The ACRF ACEMID project team and Consumer & Community Engagement Working Group developed a 3D imaging questionnaire during 2021 to determine consumer perceptions towards 3D total body imaging for melanoma early detection. Consumer input was obtained during August – December 2021, with the results being analysed during 2022.

The results have now been published in the International Journal of Dermatology. Of the 1056 participants, 95% indicated they would consider using 3D total body photography, with most thinking it would be effective for identifying suspicious skin spots (94%), monitoring lesion changes (94%), and reducing skin cancer related anxiety (90%).

Consumer Forums

Two Consumer Forums were held by the ACRF ACEMID project team during 2022.

The first Consumer Forum, held in March 2022, addressed the topic of 'Skin cancer photography: consent & protecting your privacy'. Participants were asked to respond, via online polls and discussion, to a series of hypothetical scenarios about how images could potentially be used for research, AI development and their own clinical care.

The results from this forum have been published in the Australasian Journal of Dermatology. As the potential sensitivity of images increased, an increasing proportion of participants reported they would have reservations about sharing such data for multiple purposes. A greater proportion reported reluctance to share images on public platforms and for business-centric uses, such as social media, classroom teaching, public databases and AI, whereas there was higher comfort for use in clinical or research settings.

Due to the concerns participants in our forum raised about control over their images and a lack of current guidelines, researchers and healthcare providers should prioritise privacy concerns to facilitate uptake, by providing clear privacy policies and safeguards, including outlining transparently any secondary uses of data.

The second Consumer Forum, held in November 2022, addressed 'The future of melanoma screening'. This forum provided consumers with an update about the Cohort Study, followed by presentations and discussions around our vision for a targeted melanoma screening program and new technologies that could be incorporated in melanoma screening and surveillance in the future.

Melanoma Screening Consumer Forum image (Nov 2022)

ADDITIONAL ACHIEVEMENTS

The ACRF ACEMID project team is comprised of over 40 investigators and continues to expand as the 3D total body imaging sites are established and additional research studies are initiated.

The project team are actively contributing to the development of the next generation of melanoma and skin cancer researchers, mentoring 11 post-doctoral researchers/clinical fellows and 16 PhD/MPhil students during 2022 - 2023.

There have been five peer reviewed journal articles published since 2022, with another 2 articles undergoing review. Many more publications are anticipated once the research data starts to accumulate from the Cohort Study and IMAGE Trial.

FUNDING WISHLIST

The additional research funding obtained to date allows the ACRF ACEMID research team to advance several key project objectives.

However, additional funding is required to support currently under resourced project objectives, to expand and enhance original project outcomes, and to maintain current operations. Some examples include:

- Development of robust, tailored telehealth solutions for the early detection of melanoma, utilising the 3D total body imaging systems and telemedicine research network established for the ACRF ACEMID project. This is of particular relevance for regional and rural areas of Australia where specialist expertise and care is not readily available.
- Genomics projects to collect and analyse participant samples for genetic markers indicative of melanoma risk, and to validate approaches for incorporating this genetic information into targeted melanoma surveillance protocols.
- Proteomic projects to collect and analyse participant samples for prognostic markers of melanoma and skin cancer.
- Progression of the project's Health Informatics research around standards development for 3D total body imaging data, and interoperability and integration of this data with clinical information systems spanning numerous health jurisdictions.
- ACRF ACEMID site personnel support, supplementing the sites in-kind contributions, to boost site research activity and data collection.
- Operational personnel support, across participating states, to ensure a well managed 3D total body imaging network is maintained for maximal research output.

Sunshine Coast (March 2022)

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