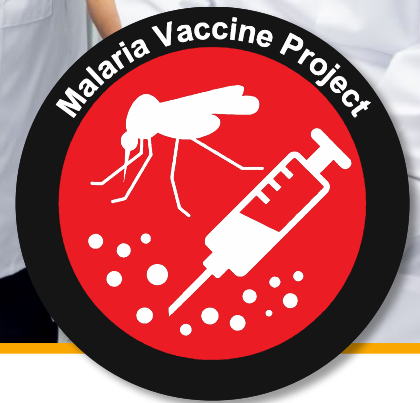


BREAKING NEWS:
Toxicology results are in!



MALARIA VACCINE PROJECT

NEWSLETTER Issue #1 - 2024



OUR HISTORY

In 2015 Sam and PDG Sandy Doumany attended a Rotary Against Malaria Conference, with Dr Danielle Stanisic from the Institute for Glycomics as the Guest Speaker. Danielle spoke about Malaria Vaccine research led by herself and Professor Michael Good AO at the Institute. She mentioned that their Laboratory needed a Separator which would cost \$8000.

Sam took that on board and approached PDG Graham Jones to see if the money required could be raised. Within a week, Graham, Sam and other Rotarians had raised the funds.

The Griffith Rotary Satellite Club was in the formation period and the cheque was presented to Dr Danielle Stanisic (a prospective member) at the next meeting. The Rotarians felt this sent a message to new members:

“This is the power of Rotary”

After learning more about Professor Michael Good and Dr Danielle Stanisic’s research journey, a core of Rotarians developed a passion to be part of the quest to save the lives of so many men, women and children and eliminate Malaria from the world.

In 2016 Gerard Brennan had discussions with the Governor General’s Office in Canberra which led to the Governor General, Sir Peter Cosgrove, launching the Malaria Vaccine Project at a function in the Institute for Glycomics on 27 March 2017.

COMMITTEE CHAIR

PDG Sandy Doumany OAM

COMMITTEE

Neil Jones (Treasurer)

Laraine Brennan OAM (Secretary)

Gerard Brennan OAM

Hon Sam Doumany AM

Teresa Dawson

Karin Kolenko

PDG Ross Smith

PDG Dai Mason

Bruce Howlett

PDG Harry Bolton

PDG Jeff Egan

NATIONAL AMBASSADOR

The Honourable Anna Bligh AC

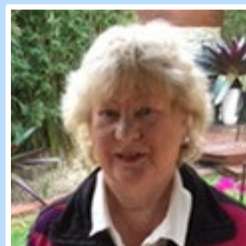
MALARIA VACCINE PROJECT NEWSLETTER COMMITTEE



Gerard Brennan OAM
Chair



Hon Sam Doumany AM
Committee Member



Laraine Brennan OAM
Committee Member



James Endelman
Advancement Manager
Institute for Glycomics

MALARIA IS ONE OF THE WORLD'S DEADLIEST DISEASES AND REMAINS A MAJOR GLOBAL HEALTH ISSUE



Malaria causes fatigue, fever, seizures and, if untreated, coma and death.



Malaria is spread easily by the bite from an infected *Anopheles* mosquito and is endemic in tropical countries and regions such as Latin America, Asia and the sub-Saharan Africa.



One person dies from malaria every minute.



Over the past 5 years, it is estimated there have been over **1 billion** cases of malaria worldwide.

An estimated **2.9 million** people died from the disease.

76% of those deaths were children under 5 years of age.



Malaria has a devastating impact on the economies of some of our closest neighbours. It is our responsibility as part of the global community to help end malaria.

IMAGINE BY 2028 WE HAVE A GAME CHANGING, PROVEN VACCINE, AND THAT BY 2033 IT CAN BE ROLLED OUT TO THE COUNTRIES THAT NEED IT MOST.

For the past 10 years Griffith University, in partnership with Rotary, has been developing a vaccine candidate that could make this a reality.

Our team at the Institute for Glycomics is about to embark on a clinical trial for this game changing vaccine and we are now seeking philanthropic partners to support the vaccine manufacture, ahead of Phase II trials.

Will you join us in this vital journey to end malaria – for good.



CHAIR MESSAGE

PDG Sandy Doumany OAM
Chair, Malaria Vaccine Project

Welcome to the first newsletter of 2024.

My New Year wish for 2024 is for us all to renew our support for the Malaria Vaccine Project. As Chair of the Malaria Vaccine Project, we are embarking on an extremely exciting year ahead and I implore you to not only continue this journey with us, but dig deep to double down on your fundraising for this critical need and in turn, double the impact.

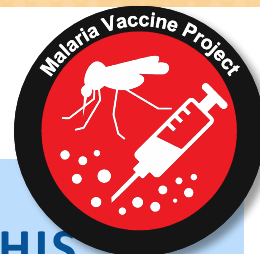
"Challenging times often lead to the best outcomes, for it's in adversity that resilience is forged, creativity flourishes, and the seeds of greatness are sown." These are challenging times for many and through our own individual struggles, we must never lose sight of those that others are facing, especially when it is the difference between life and death for so many including pregnant women and children globally.

SPOILER ALERT! The research team are at a critical stage with successful results of the toxicology study being recently attained! You can read more about this on page 5 & 6. This means that the team, led by Professor Michael Good AO and Associate Professor Danielle Stanisic have taken a momentous step forward and are poised to start the trials this year, with phase I being onshore in Australia. There is a lot going on, but the toxicology tick of approval and the giant leap forward toward a malaria free future, poses a pressing need for continuity of support and funding, particularly for vaccine manufacture for these trials.

So many of us have the joy of bringing little babies into our families, to join us in experiencing good health, love, education, and freedom, and in our society, we may take these basic human rights for granted. It is our responsibility to band together to address malaria once and for all, to bring us to the day that over 608,000 children who die from Malaria each year, can look forward to a healthy future.

We look forward to Professor Michael Good AO presenting at the District 9640 Conference on the 18th May 2024 for what is set to be an extremely important update on this Project. I hope to see many of you there.

PDG Sandy Doumany OAM



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RESEARCH UPDATE

Professor Michael F. Good AO DUniv

*Head, Laboratory of Vaccines for the Developing World,
Institute for Glycomics, Griffith University*

Our 'whole parasite' malaria vaccine passed a major hurdle with the completion of the formal toxicological evaluation of the vaccine by an independent clinical research organisation. The vaccine, containing purified cultured *Plasmodium falciparum* parasites, is designed to significantly minimize the morbidity and mortality associated with malaria – a disease which kills over 600,000 young children each year. The 'Investigator Brochure' is now being prepared for the clinical trial, which is due to commence later this year.

The technology that we developed, and which underpins the design of this malaria vaccine, is applicable to other vaccines and this led us to a novel design for a Babesia vaccine. Babesiosis, a disease very similar to malaria, is a tick-borne disease, and while it does affect humans, in Australia it is predominantly a disease of cattle. Globally ~400 million cows are at risk of babesiosis. With Australian Research Council funding, we are embarking on a trial of our whole parasite vaccine, which will be able to be freeze-dried to a powder (like the malaria vaccine), facilitating easy uptake by farmers in remote parts of the country.

The progress of the malaria vaccine is due to the superb efforts of many. I would like to acknowledge the hard work and dedication of all my laboratory staff and students, and the wonderful leadership of the Malaria Team by Assoc. Professor Danielle Stanisic. I also thank the amazing members of the Rotary Malaria Vaccine Committee, superbly led by Mrs Sandra Doumany OAM, and the hard-working admin group at Glycomics. Rotary have now raised and leveraged over \$2.8M - a staggering amount of money - enabling us to proceed with the malaria vaccine trial.

I am so delighted to mention that our former Chair, Graham Jones, was awarded an Honorary Doctorate of Griffith University (DUniv) at a graduation ceremony on the Gold Coast last December. Graham's lifetime contribution to education, the University, Rotary and many other community causes has been phenomenal. At the same ceremony it was wonderful to see our student, Winter Okoth, graduating with her PhD. Winter's PhD was to test the malaria vaccine in an animal model. She produced an excellent thesis and her results were published in a leading international journal, *mBio*. Winter, who is from Kenya, knows first-hand the devastating impact that malaria has on young children and families. I was very honoured to recently receive the Dr John Raftos Medal and a \$50,000 award from the National Foundation for Medical Research and Innovation (NFMRI). NFMRI has supported our malaria vaccine program at a critical time in its development. The award is being matched by the Institute for Glycomics and will be used to upgrade our immunological technology within the lab.





PROGRESS WITH PLASPROTECT: WHERE WE ARE, WHAT'S NEXT AND WHERE WE HOPE TO BE 12 MONTHS FROM NOW

Associate Professor Danielle Staniscic, PhD
*Research Leader and Principal Research Fellow,
Institute for Glycomics, Griffith University*

In exciting news, we are now entering the home stretch in our preparations for the upcoming Phase I trial for the field-deployable form of PlasProtect. It will be a very busy time over the coming months.

We have recently been advised that the formal pre-clinical toxicology study for our field-deployable vaccine formulation has been completed and we have received the official report stating that our vaccine is safe and well tolerated in pre-clinical models. These results support the evaluation of our field-deployable PlasProtect vaccine candidate in a Phase I clinical trial.

With this recent news, we are continuing our preparations for the Phase I trial. This includes consulting with a statistician to ensure that our clinical trial is properly designed and powered to be able to evaluate our endpoints of interest which are primarily safety and immunogenicity in malaria-naïve adults. Once the number of study participants and study design is confirmed, we will work with our clinical trial provider in Southeast Queensland, Australia, to finalise study documents including the study protocol, investigator's brochure and the patient information and consent form. These documents will be submitted to a Human Research Ethics Committee to seek approval for the conduct of our Phase I trial. Additionally, we will submit a study notification to the Therapeutic Goods Administration, which is Australia's regulatory agency for therapeutic goods that will be administered to humans.

In parallel, we are commencing GMP-compliant manufacture of the *P. falciparum* parasites that will be included in the vaccine. For this, we will be using our new Wave25 bioreactor, which I have mentioned in a previous newsletter. This will easily facilitate the scale-up of our vaccine production. We are also in the process of finalising the agreement to purchase the clinical-grade liposomes that are also part of the vaccine formulation.

We anticipate that the Phase I trial will commence in the second half of this year and that it will take up to 12 months to recruit and complete the vaccinations of the different groups of study participants. Each group will receive different numbers of parasites in their vaccine using a dose-escalation study design. During the study, we will be collecting blood samples from the study participants so that we can store plasma and white blood cells that we will use to assess their immune response to the parasite. We are currently developing novel assays to assess the functionality of the cellular immune response. So, in 12 months, we will be in the middle of our Phase I trial and hope to have preliminary results supporting the safety and immunogenicity of the vaccine.

Pathway to success

2013

THE FIRST PRE-CLINICAL STUDIES evaluating PlasProtect were published. These studies demonstrated that PlasProtect was broadly protective against different malaria parasite strains.

2014-2015

GRIFFITH UNIVERSITY CONDUCTED a world-first pilot study to evaluate PlasProtect in malaria-naïve human volunteers demonstrating that it was safe and could stimulate a parasite-specific immune response.

2018 – 2020

A WORLD-FIRST PILOT CLINICAL STUDY CONDUCTED BY GRIFFITH UNIVERSITY to evaluate whether PlasProtect could stop malaria-naïve individuals from developing malaria infection. The majority were completely protected from developing a malaria infection.

2024

WITH THE SUPPORT OF KEY PHILANTHROPIC PARTNERS Griffith University will conduct a Phase I clinical study to evaluate a field-deployable version of PlasProtect in malaria-naïve human volunteers **COMMENCING IN JANUARY 2024 WITH A DURATION OF 18 MONTHS.**

2028 – onwards

GRIFFITH UNIVERSITY WILL FORM part of a global consortium to roll out and evaluate PlasProtect across multiple sites in malaria endemic countries.

2015

THE RESEARCHERS PUBLISHED details of the first cultured malaria cell banks that would be used to manufacture PlasProtect for use in clinical studies.

2017

THE MALARIA VACCINE PROJECT was launched as a fundraising partnership between Rotary District 9640 and Griffith University to support further development of the malaria vaccine.

2021

THE GRIFFITH RESEARCHERS PUBLISHED pre-clinical studies demonstrating the efficacy of the field deployable form of their whole parasite blood-stage malaria vaccine in the prestigious journal mBio.

JANUARY 2024

The clinical-grade PlasProtect vaccine has successfully passed mandatory toxicology assessment and will now proceed to a full Human Research Ethics submission to enable commencement of the clinical trial.

2025 – 2027

OUR CORNERSTONE PARTNERS AND A LEADING GLOBAL PARTNER WILL CONDUCT a Phase II clinical trial to evaluate PlasProtect in a malaria endemic country.

FUNDING REQUIRED: \$29M

ROTARY SUPPORTED POSTDOCTORIAL SCHOLAR UPDATE - DR. GUILHERME DE SOUZA

My arrival at Griffith University marked the beginning of an exciting chapter in my life. The transition from Brazil to Australia was smooth, thanks to the invaluable support provided by the Institute for Glycomics and Rotary members. While the distance from Brazil can be daunting, and being away from family is challenging (especially with my niece celebrating her first birthday), the opportunity to work at a world-class research centre and contribute to the development of a malaria vaccine makes it all worthwhile.

In the past five months, I have been living in a peaceful haven in Biggera Waters with a stunning view of the ocean. The neighbourhood is quiet and well-connected to the Institute via public transportation, making my daily commute hassle-free. This is my first time living outside of Brazil, and it has been an incredibly rewarding experience. The welcoming environment, friendly people, and similar climate have made me feel at home almost instantly.

Since joining the Institute, I have immersed myself in a variety of projects, including:

1. Maintaining an in vitro culture of *Plasmodium falciparum*, the parasite responsible for malaria in humans.
My prior experience with parasite cultivation allowed me to swiftly contribute to this crucial aspect of the project. This parasite plays a multifaceted role in our research, including serving as a component of the vaccine when it is evaluated in pre-clinical studies.
2. Establishing an in vitro assay to assess the function of the cellular immune response induced by the vaccine.
This assay could be useful in testing samples from both pre-clinical and clinical vaccine studies.
3. Testing a new malaria vaccine composition in mice.
While I had limited prior experience with animal work, this hands-on opportunity has been an enriching learning experience.

Overall, this journey has fostered immense professional and personal growth. I eagerly anticipate the upcoming projects and the positive impact they will have on the fight against malaria.



Dr. Guilherme de Souza
Research Fellow
Institute for Glycomics - Griffith University



RECENT EVENTS

MARION JONES'S BIRTHDAY

March 8th was a very special day for Marion Jones, celebrating her 83rd Birthday.

Her son Cameron who is out visiting from France, is a Gourmet Cook and Wine Connoisseur.

He did the catering, very ably assisted by daughter-in Law Jodie for a ladies lunch the day before, and dinner on the night of her Birthday.

Graham was looking very relaxed with having a night off from the cooking, and Marion a very happy lady.

We all wish Marion our love as she copes with the journey of treatment.

ROTARY CHARITY GOLF DAY

The Rotary Club of Hope Island are happy to donate to the Malaria Vaccine Project \$4122.25 as one of the Beneficiaries of their Charity Golf Day.

Chair Neale Butler and his committee were very happy with the success of the day, enabling them to support Rotary Projects and other community charities.



-PDG Sandy Doumany OAM



MALARIA FIRST-HAND

AN INSIGHTFUL TESTIMONIAL FROM ONE OF OUR OWN

Sam Doumany AM

Two years in Papua New Guinea as an Agricultural Field Officer acquainted me with the devastating impact of Malaria on the local people in the coastal villages of New Ireland, New Britain, Manus Island, Bougainville, Madang, Lae and the new Sepik District.



I was well prepared by the Commonwealth Health Officers in Sydney before I departed for Port Moresby in early January 1959 with information manuals and a course of Quinine based prophylaxis tablets which I continued faithfully during my tour of duty.

As well as the medication, I used mosquito nets both in my quarters at centres such as Rabaul & Kavieng and in the village bush houses while on patrol.

On returning to the mainland in 1961, I followed a further course of medication for several weeks as recommended at that time.

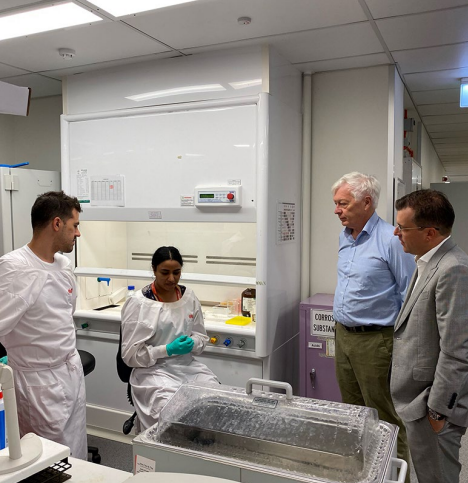
I had joined the Department of Agriculture in Queensland and became involved in farm surveys on the Darling Downs and the Wide Bay Region. Out of the blue several months later I was on the way to the Downs and a severe bout of Malaria stopped me in my tracks at Ipswich, to be rescued by colleagues and returned to Brisbane for urgent medical treatment.

That one bout of Malaria was very severe, and fortunately has not recurred. However, it certainly made me acutely aware of the drastic impact of this parasite on millions of chronic sufferers throughout equatorial endemic counties across the world.

I do not believe that we can be complacent in Australia with our tropical north so close to the New Guinea coastline.

This is why I am so passionate in supporting the Malaria Vaccine Project at the Institute for Glycomics at Griffith University. Its success will provide the means towards eliminating this scourge which carries an annual mortality rate of over 600,000 with the majority of those dying being children under 5 years old.

Sam Doumany AM



SUPPORTER LAB TOUR

A Heartfelt Thank You to Matt Gates, the Director of Ray White Sanctuary Cove!

PDG Sandy Doumany OAM, Sam Doumany AM, Professor Michael Good AO, and Advancement Manager Jamie Endelman were thrilled to recently host Matt Gates, Director of Ray White Sanctuary Cove for a tour of the Laboratory of Vaccines for the Developing World at Griffith University's Institute for Glycomics.

Matt was initially introduced to the Malaria Vaccine Project when he attended the Rotary Club of Hope Island's Black-Tie dinner in 2023. During the evening, Prof. Michael Good AO gave a particularly heart-felt speech about the devastating impacts of Malaria across the globe, and the vaccine he and the team are developing to put an end to it. Hearing Michael speak so passionately about the incidence and the promise of the vaccine development, compelled Matt to make a generous on-the-spot donation to the vaccine which was very well received.

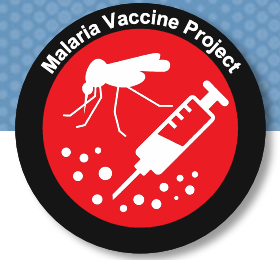
Enthusied by the work being done, Matt was intrigued to hear more and see the 'engine room' for himself.

During the tour, we shared our dedication to unravelling the mysteries of the disease, pushing the boundaries of science, and taking strides towards a healthier world, developed right here in the backyard that he sells to many, wanting to enjoy the lifestyle that the Gold Coast has to offer.

Additionally, it was a special moment to walk down memory lane and show Matt the instrument that Rotary Club of Hope Island, other Rotary Clubs and individual Rotarians helped to fund back in 2014, to which the Malaria Vaccine Project partnership with Rotary was born. The instrument, a Cell Separator, is used to purify parasitised red blood cells. This instrument has been a critical piece to the research and continues to stand proudly in use in the laboratory. It is these humble reminders that demonstrate how a conversation, a presentation and a small piece of equipment support can pave the path to what we can see on the horizon as, a malaria free future.

We are deeply appreciative of the Ray White Sanctuary Cove's generous donation to our Institute. Their support is an investment in the future of healthcare, and it will undoubtedly help us continue our critical research in the battle against malaria that affect millions globally.

Together, we are changing the world.



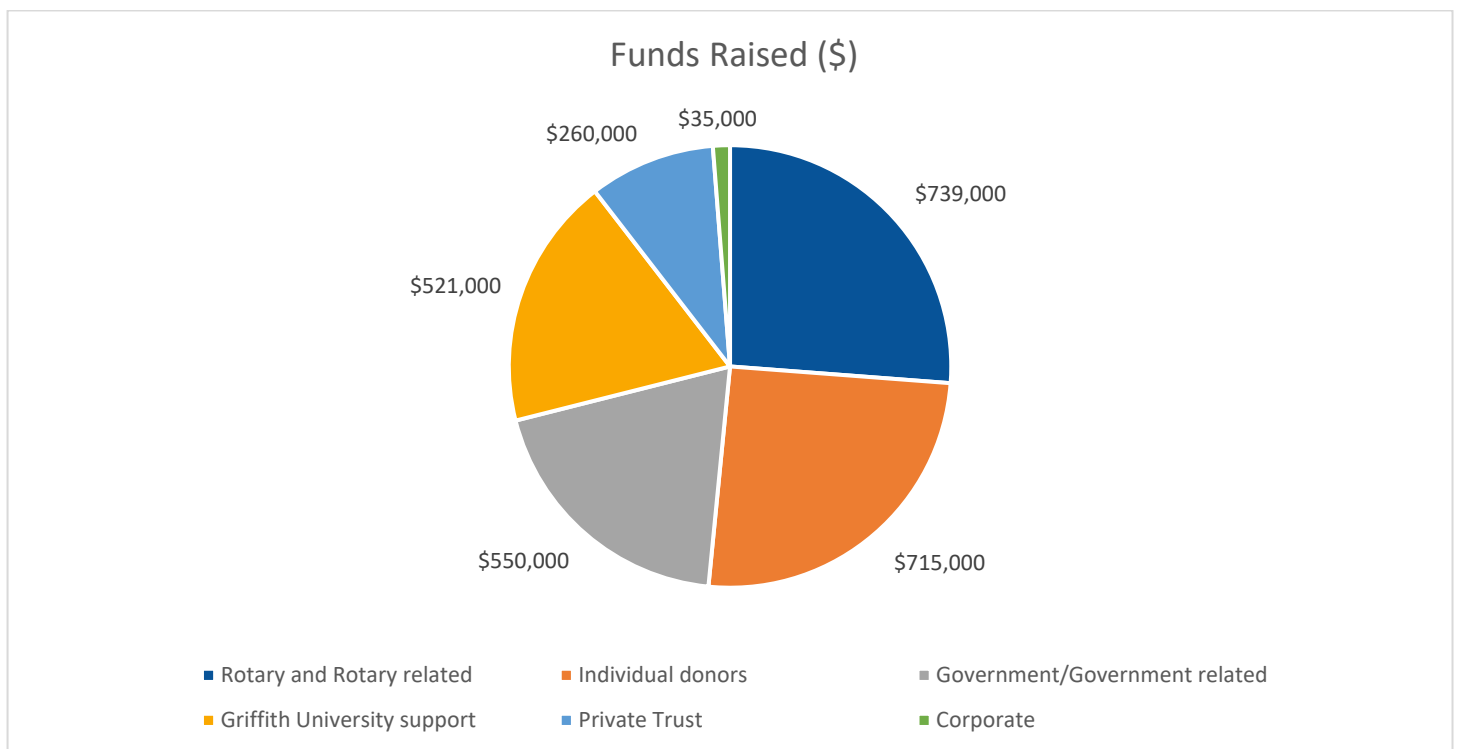
FINANCIAL UPDATE

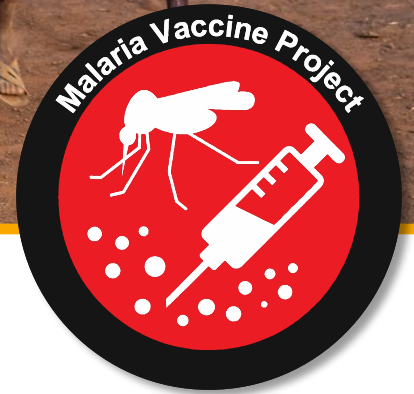
Neil Jones

Since our last update in mid-December we have experienced our usual pause in donation/fundraising activity over the holiday period and up to 20th March 2024, funds received this calendar year total only \$5,050 taking our cumulative total to \$2.820 million.

With the positive outcome of the toxicology tests and the Phase I Human Trials to commence shortly, we anticipate increased momentum for our fundraising activities including a greater focus on the corporate sector.

Contributions from individual Rotary Clubs continues to be led by Hope Island (\$121,000), Surfers Paradise (\$39,000) and Hornsby (\$36,000).





WANT TO LEARN MORE?

Come and visit our malaria lab at Griffith University.

Contact Jamie Endelman, Advancement Manager at j.endelman@griffith.edu.au

OUR PARTNERS



malariavaccineproject.com • facebook.com/malariavaccineproject