



MALARIA VACCINE PROJECT

NEWSLETTER December 2023 | ISSUE 21



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 (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



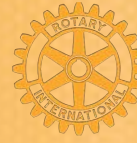
Hon Sam Doumany AM
Committee Member



Laraine Brennan
Committee Member



James Endelman
Advancement Manager
Institute for Glycomics



CHAIR MESSAGE

PDG Sandy Doumany OAM
Chair, Malaria Vaccine Project

Welcome to the fourth Newsletter for 2023,

Where did that 12months go? It only seems like yesterday that I took over the role of Chair of the Malaria Vaccine Committee and yet, as I reflect, we have achieved a lot in the research, fundraising efforts and the exciting appointment of our Postdoctoral Scholar, Dr Guilherme de Souza from Brazil. Guilherme joins the research team with an array of experience, having already worked on a Malaria Research Program.

I would like to say a big thank you to all of our loyal financial supporters in District 9640, the wider circle domestically in Australia and our International support overseas.

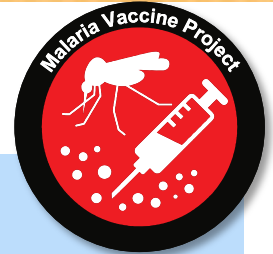
A special thank you to The Rotary Club of Surfers Paradise (for including the Malaria Vaccine Project as their beneficiary of fundraising efforts at their annual Race Day), and The Rotary Club of Hope Island (for the spectacular Black-Tie Dinner in addition to the funds raised earlier in the year). Their fundraising functions for the Malaria Vaccine Project were very successful.

At the Black-Tie Dinner, Professor Michael Good AO successfully bid on (and won under the hammer) a 4-day cruise to Hobart and back on the Royal Princess in November. He asked if anyone would like to join him and 2 couples obliged, all having a wonderful time and enjoying the fun and friendship at sea.

A big thank you to the committee members of our Project for their ongoing loyalty and hard work. All have a role to play and it is the passion for the project and the impact after six years, that keep us working hard for success.

On behalf of the Committee, I wish you all a very Happy Christmas & New Year.

PDG Sandy Doumany



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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*

Dear Malaria Vaccine Supporters,

I would like to thank Sandra and all the members of the Committee for their wonderful commitment and support over the last year. The Committee has directly raised a further \$358,351 over the last 12 months in very difficult financial times and that is a wonderful achievement.

With the endorsement of the Committee and the University, our National Ambassador, the Hon. Anna Bligh AC, travelled to Perth with Associate Professor Danielle Stanisic, Marcus Ward (Vice President of Advancement at Griffith University) and I, to engage with members of the Australia-Africa Minerals and Energy Group to discuss our vaccine research and plans to undertake a Phase II trial in a malaria-endemic country (such as Uganda or Tanzania). I would like to register a special thanks to Ms Bligh for her passionate commitment to our cause and for her very strong words of endorsement at the dinner in Perth. I would also like to record my special thanks to Mr Bill Repard (Paydirt Media) who generously hosted the dinner and to all the guests who attended. It is worth noting that we have been invited to return to Perth next year to address their major conference and have also been invited to contribute an article to the highly circulated magazine, Paydirt. I am optimistic about support that will help move the vaccine forward.

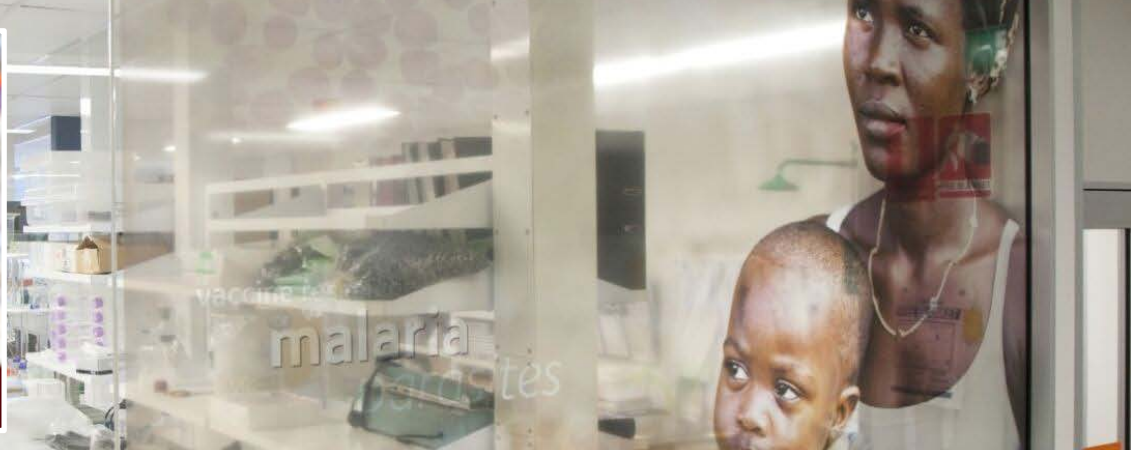
Next year promises to be a busy and exciting time for our malaria vaccine research. The results of the 'toxicology' will be available in January, and we will then be in a position to move ahead with the eagerly awaited Phase I clinical trial. As that progresses, we will be looking to manufacture hundreds of vaccine doses for the Phase II trial which will follow (funding permitting).

This week, we were delighted to see our former Chairman, Emeritus Professor Graham Jones AM, be awarded a Doctorate of the University at a gala graduation ceremony on the Gold Coast. Graham was our Chair for 6 years, but additionally, has contributed enormously to the University and well beyond over a stellar career. He enthralled the graduating class with his wonderful address on the virtues of passion and commitment to achieving life's goals, drawing on fascinating analogies of sports heroes and mathematical genius, Andrew Wiles!

I would like to give a great vote of thanks to Danielle and all the members of the malaria team at Institute for Glycomics. They are a truly wonderful and very hard-working team who all share our passion for developing a malaria vaccine and who love science. I also thank our Advancement Manager, Jamie Endelman and Senior Advancement Manager, Nina Kristensen, for their fantastic support for the Malaria Vaccine Project Committee and for our broader fund-raising efforts.

All the very best to everyone for Christmas, holidays, and the New Year!

Professor Michael F. Good AO



HOW IS A VACCINE DEVELOPED?

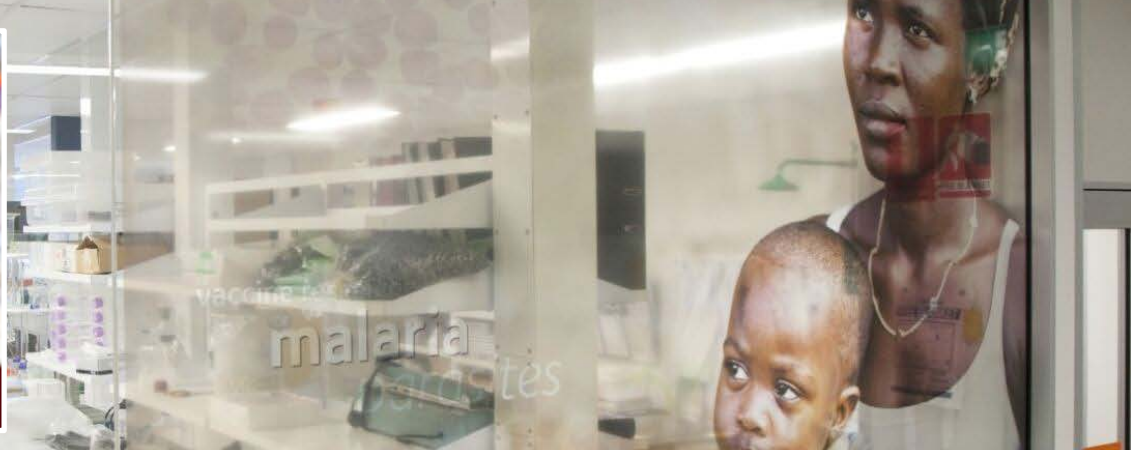
Associate Professor Danielle Stanisic, PhD
*Research Leader and Principal Research Fellow,
Institute for Glycomics, Griffith University*

Immunization is one of the most successful and cost-effective public health interventions. The World Health Organisation estimates that immunization programs prevent 4-5 million deaths every year. There are now preventive vaccines against >20 different life-threatening diseases.

A vaccine must progress through different phases of evaluation to demonstrate that it is safe and effective before it can be licensed and available to the general population. Concerns with safety, immunogenicity (ability to stimulate an immune response) or effectiveness (also known as efficacy) can halt the vaccine development pathway at any point.

Stages of vaccine development:

- I. **Discovery (2-5 years):** This involves laboratory-based studies to identify the vaccine antigen/s (the substance that will stimulate the immune response).
- II. **Pre-clinical development (2-3 years):** The vaccine is evaluated in pre-clinical models (both laboratory and animal models) to provide information on safety, immunogenicity, and efficacy. Toxicological studies are undertaken to look for any harmful effects. Reproducible vaccine manufacturing processes are also developed. At the end of this process, if positive results are obtained, an application can be submitted to a Human Research Ethics Committee and the appropriate regulatory agency (e.g. the Food and Drug Administration, the European Medicines Agency and the Therapeutic Goods Administration) to begin clinical evaluation in humans.
- III. **Phase I clinical trials (2 years):** involve evaluating the vaccine in <100 healthy adults to confirm immunogenicity of the vaccine in humans and that it is safe to progress to a Phase II trial. Common side effects e.g. soreness at the vaccination site, muscle pains, headache and fever are usually identified here. Different doses of the vaccine may be evaluated. If human challenge infection models are available for the pathogen of interest (e.g. for malaria; Stanisic et al 2017 doi: 10.1128/IAI.00479-17), vaccine efficacy can be evaluated in Phase Ib trials. These studies are a way to obtain preliminary efficacy data on the vaccine prior to undertaking larger and more expensive Phase II and III trials in the field under conditions of natural exposure to the pathogen that the vaccine targets.
- IV. **Phase II trials (2-3 years):** involve hundreds of participants and are typically undertaken in populations that the vaccine will eventually be used in. Here, immunogenicity and safety are also evaluated. Phase IIb trials are like "mini Phase III studies" and may be undertaken to obtain data on vaccine efficacy in a few hundred individuals at a single site under conditions of natural exposure.



- V. Phase III trials (5-6 years): involve evaluating the safety and efficacy of the vaccine in thousands of individuals under conditions of natural exposure at multiple sites. These trials involve comparing the effectiveness of the vaccine against a placebo group. If fewer people who received the vaccine develop the disease the vaccine targets, compared with those who received the placebo, this is evidence that the vaccine prevents the disease. After a successful Phase III trial, the safety and efficacy data are reviewed by the appropriate regulatory agency, and they determine whether the vaccine will be licensed for use in the general population.
- VI. Phase IV trials/post-licensure safety studies: Even post-licensure, vaccine safety continues to be monitored over a much longer period of time using real-world data to identify rare side effects or those that occur after long periods following vaccination. As Phase I-III trials involve relatively small numbers of individuals, they only give us information on common side effects (>1% of the population). Detection of very rare side effects (<0.01% of the population) requires information collected from hundreds of thousands (or even millions) of individuals.

Typically, vaccine development follows the conventional pathway/timeline outlined above, taking up to 10 years to progress from Phase I trials through to vaccine licensure. During the COVID-19 pandemic, vaccine development was accelerated, with a 10-11 month timeline, due to the urgent need for a safe and effective vaccine. This was only possible due to factors including unprecedented levels of public funding, international collaborative efforts, pre-planning for vaccine manufacture and overlapping/combined phases of clinical trials. It should be noted that this compressed timeline was not at the expense of vaccine safety and effectiveness evaluations. It is hoped this valuable experience gained during the COVID-19 pandemic will help to accelerate the development of new vaccines in the future.

Events

TASMANIA CRUISE RECAP

At the Rotary Club of Hope Island's Black-Tie Dinner, Professor Michael Good AO successfully bid on an auction item, a 4-day cruise from Sydney to Hobart and back on the Royal Princess in November. Joining Michael was his partner Jenny, as well as Sandy and Sam Doumany, along with Sandy's nephew Andrew and his wife Charmaine.

The cruise departed Melbourne and travelled to and from Hobart over 4 wonderful days aboard the 'Royal Princess', a 330m cruise ship with a capacity of 3,600 passengers.

The days were wiled away eating, talking and enjoying each other's company.



MARK YOUR CALENDARS! FUTURE EVENTS for 2024

- Golf Day
15 March 2024 (tbc)
The Links, Hope Island
- Boat Show
23-26 May 2024
Sanctuary Cove



AN EXCITING NEW PARTNERSHIP

COLLABORATION AND COMMUNITY SPOTLIGHT

Marcus Ward

*Vice President, Advancement
Griffith University*

Paydirt Media the founder of Africa Down Under (ADU), announced a new partnership with the Australian Malaria Vaccine Project, based at Griffith University in Queensland. This collaboration aims to build a consortium of support from leading businesses and individuals operating in sub-Saharan African countries and other regions where malaria is prevalent.

The Honourable Anna Bligh AC, National Ambassador for the Malaria Vaccine Project (CEO of the Australian Banking Association and former Premier of Queensland), along with the project's research team—Professors Michael Good AC and Danielle Stanisic and Marcus Ward, Vice President of Advancement flew to Perth to discuss the rollout of the Malaria Vaccine Project with leading companies and executives in the African resources space. This dinner was generously hosted by Bill Repard, Executive Chairman; Dominic Piper, Editor; and Angelique Julien of Paydirt Media.

There was a positive response from those corporate leaders present, many of whom have experienced first-hand the debilitating effects of malaria and the devastating consequences and toll upon the communities in which they are based and operate. They applauded the experienced and passionate Australian scientists leading this project and appreciated the great strides towards developing a cost-effective, single dose vaccine that can be easily stored and transported in logistically challenged environments. Malaria has a debilitating effect on people living in many developing economies who lack the healthcare and public administration systems that we are privileged to enjoy. The success of a vaccine like this would be life-changing for millions of people.



Q&A

Q&A WITH BRUCE HOWLETT

Does Australia experience cases of malaria?

Australia was declared malaria-free in 1981, which means we do not have localised transmission or "spread" of malaria. In saying that, we do have mosquitoes in the Northern parts of Australia that are capable of transmitting the malaria parasite. We also have up to 800 imported cases of malaria every year. These are individuals who have contracted malaria while on holidays or business in malaria endemic areas.

Can Malaria be cured?

Malaria can be cured. If a person is suspected of having malaria, it is important that the diagnosis is confirmed early, followed treatment. Different tests can be used to confirm this diagnosis. These include a Rapid Diagnostic Test, a blood smear and a more sensitive test known as a PCR test which can detect very low levels of parasites in the blood.

Can Malaria re-occur?

This depends on which species of the malaria parasite you are infected with. The majority of human malaria parasites, including the most deadly species, *Plasmodium falciparum*, can be successfully treated with drugs that kill the parasites in the bloodstream and in these instances, malaria will not reoccur. Two species of malaria parasite, *P. vivax* and *P. ovale*, have latent forms ("hypnozoites") that can persist in the liver. Treatment with specialised drugs such as primaquine or tafenoquine is needed to kill these liver forms and prevent reoccurrence weeks or even months after the initial bout of malaria.

Could Malaria become endemic in Australia once again?

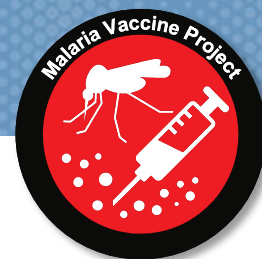
The answer is most definitely, yes. In Northern parts of Australia we have mosquitoes that can spread the malaria parasite. It would only take an unknown infected person to be bitten by a suitable mosquito the spread is possible. Parts of the US have recently recorded an increase in local cases of malaria due to this.

How can I prevent contracting Malaria if I travel overseas?

If you are travelling to a Country with known cases of malaria, it is important that you consult with your Medical Practitioner who will almost certainly prescribe a suitable medication to be taken, before, during and after you return to Australia.

Could Malaria be eliminated from the World one day?

Just like Polio it is possible. It will require suitable well managed vaccination programs combined with current practices such as prompt diagnosis and treatment of infection, the use of insecticide impregnated mosquito nets and continued indoor insecticide spraying of dwellings and water ways.



FINANCIAL UPDATE

Neil Jones

As at 15 December total fundraising for The Malaria Vaccine Project had reached \$2,814,916, an increase of \$358,351 this calendar year.

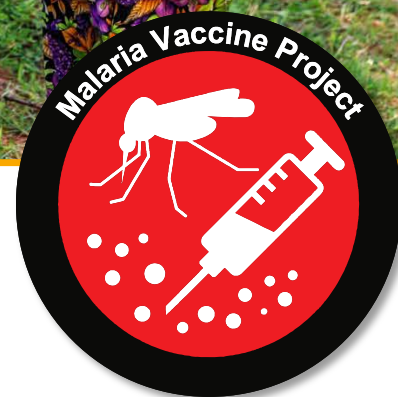
SOURCE OF FUNDS

Rotary District 9640 Clubs and Individual Rotarians	\$ 426,814
Other Australian Rotary Clubs and related	251,197
International Rotary Clubs, The Rotary Foundation & related	55,839
Total Rotary	\$ 733,850
Individual Donors	714,516
Private Trust	260,000
Corporate	35,000
	\$1,743,366
Gold Coast 2018 Legacy Committee	50,000
Australian Government Medical Futures Fund	500,000
Griffith University Matching Funds	521,550
	\$2,814,916

ROTARY CLUB CONTRIBUTIONS

The top 5 Rotary Club contributors are:

Hope Island	\$120,514
Surfers Paradise	38,697
Hornsby	35,628
Gold Coast	25,638
Engadine	20,000



OUR PARTNERS



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