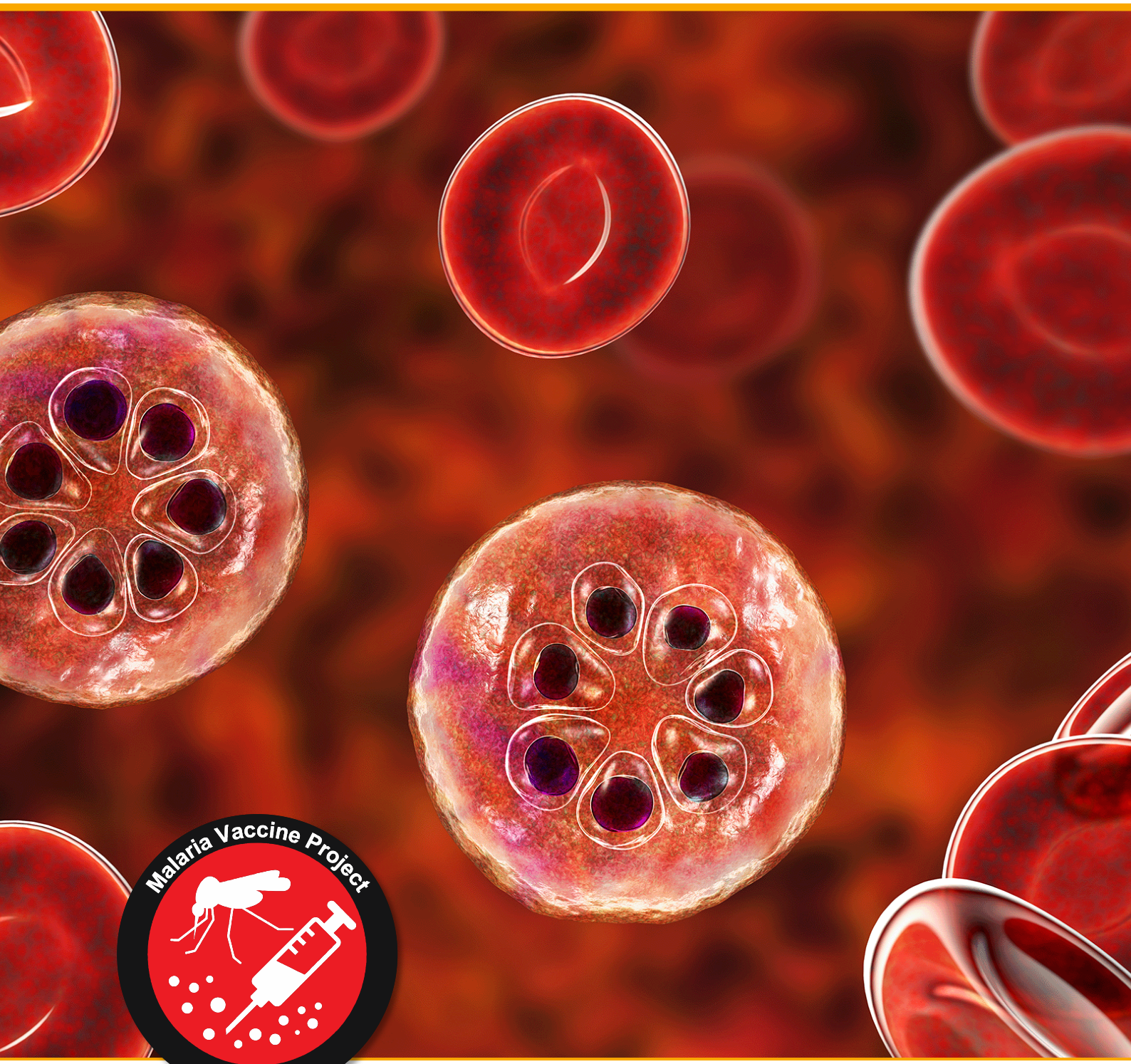
GRIFFITH UNIVERSITY | INSTITUTE FOR BIOMEDICINE AND GLYCOMICS

Rotary District 9640



MALARIA VACCINE PROJECT

NEWSLETTER Issue #1 - 2025

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 Biomedicine and 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.

Rotary
District 9640

CHAIR MESSAGE

PDG Sandy Doumany OAM
Chair, Malaria Vaccine Project

It seems a bit late to be saying Happy New Year, but this is our first Newsletter for 2025.

I'd like to begin by firstly hoping all of our readers, friends and families In the Northern NSW and Queensland regions that were recently affected by Cyclone Alfred, as well as those In Northern QLD affected by the flooding, are all doing as well as possible and that the clean-up and repair efforts are speedy. In times like these the community spirit and togetherness that we all foster are hugely important.

With that said, we trust that 2025 will be an exciting year for our Project moving forward.

The District 9640 Conference will be held at Southport Sharks on the Gold Coast 28th -30th March and Professor Michael Good AO will be a Guest Speaker and we will be manning a stand in the House of Friendship with up-to-date information on the Malaria Vaccine Project, so make sure you call in and say hello.

We are at a stage that we are able to see the light at the end of the tunnel, our passion is to see the saving of hundreds of thousands of women & children lives across the equatorial regions of the world.

FUNDRAISING IDEAS

As we enter 2025, please think of ways to fundraise for the Malaria Vaccine Project. Dinners, BBQ's, Golf Days, Trivia Nights and many more.

If you require a Guest Speaker or advice for a Fundraiser, please do not hesitate to contact me directly.

PDG Sandy Doumany 0418150240 srmd@bigpond.net.au

RESEARCH UPDATE

Professor Michael F. Good AO DUniv
Head, Laboratory of Vaccines for the Developing World,
Institute for Glycomics, Griffith University

I hope all our readers had a safe and joyful Christmas/New Year season, and are as excited as we are about what the year ahead holds for the malaria vaccine project.

The upcoming months are brimming with promise for our PlasProtecT malaria vaccine. After being carefully produced in the GMP-compliant facility at Griffith University, the vaccine has passed a crucial sterility test, building on its success in toxicological testing last year. With these milestones achieved, we are now ready to prepare the Investigational Brochure and Clinical Trial Protocol, which will be submitted for Ethics approval to launch the trial in Q3 this year.

As we gear up for this ground-breaking moment, it's important to reflect on the stark realities laid out in the latest WHO Malaria Report, released in December 2024. According to the most recent global data for 2023, there were 263 million malaria cases, a worrying increase from the previous year's 249 million cases. While the estimated death toll of 597,000 is slightly lower than the 608,000 deaths in 2022, the numbers remain unacceptably high.

Looking ahead, challenges loom that could further impact malaria case numbers. The WHO reports that humanitarian emergencies—caused by conflict, violence, and natural disasters—disproportionately affected malaria-endemic populations in 2023. Global warming, coupled with rising humidity levels, has emerged as a major driver in the malaria death rate. On top of that, the spread of drug resistance in both Africa and Asia, along with rising mosquito resistance to insecticides, threatens to derail progress. Alarmingly, the highly infectious Asian mosquito, Anopheles stephensi, has now infiltrated the Horn of Africa, fuelling new malaria cases in urban centers. If this mosquito spreads further across the continent, the consequences could be catastrophic.

Current malaria vaccines, RTS,S and R21, target the sporozoite stage of the parasite's lifecycle, offering only partial protection. While they have contributed to a 22% reduction in severe malaria hospitalizations in vaccinated children, they are far from the silver bullet needed.

Encouragingly, global investment in malaria research increased by 9% to reach US$690M in the past year. However, more than a quarter of this funding came from the US National Institutes of Health (NIH). We are fortunate to receive some NIH support through a grant where Danielle serves as Principal Investigator. Moving forward, we hope this critical funding will not be reduced by shifts in US government policy.

All of this underscores the growing significance of the Griffith University Rotary Malaria Vaccine Program. Our PlasProtecT vaccine takes a unique approach by targeting both the blood stage of the malaria parasite and reducing disease. This strategy complements the RTS,S and R21 vaccines, which only address the sporozoite stage. Moreover, because our vaccine contains all the proteins of the malaria parasite, vaccine resistance (akin to drug resistance) could never develop.

As we look ahead, I'm pleased to share that later this year, I will be honored to become Emeritus Professor. The University will continue to support our research efforts, with Danielle and I, alongside the unwavering backing of Rotary, continuing to lead the charge in advancing the PlasProtecT malaria vaccine. We are truly grateful for your ongoing and incredible support of this life-saving initiative.

Michael

RESEARCH UPDATE

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

Last year, the Rotary Club of Cleveland invited me to one of their weekly meetings to speak about the Malaria Vaccine Project. Following this, I spoke at their "High tea" event to raise awareness about malaria. In February 2025 I was invited back to the club to receive a very generous donation of $4205 to the Malaria Vaccine Project. This funding will contribute to an upcoming Phase I clinical trial of the field deployable PlasProtecT malaria 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

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.

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.

2025

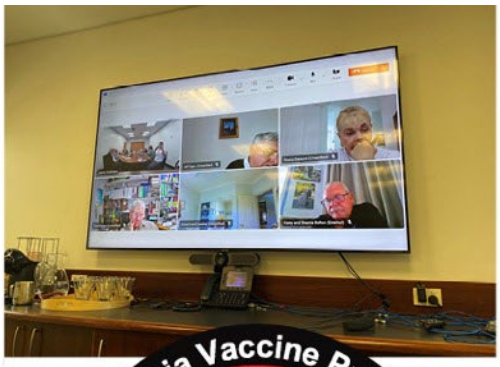
WITH THE SUPPORT OF KEY PHILANTHROPIC PARTNERS Griffith University will conduct a Phase I clinical study to evaluate a field-deployable version of PlasProtecT in malaria-naive human volunteers

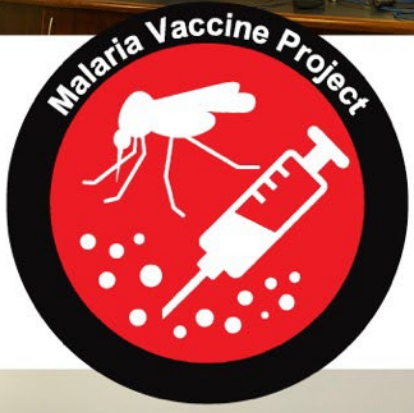
COMMENCING JUNE 2025 WITH A DURATION OF 12 MONTHS.

2026 – 2028

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





MALARIA VACCINE PROJECT - COMMITTEE IN ACTION

The Malaria Vaccine Committee, chaired by PDG Sandy Doumany OAM, plays a pivotal role in the ongoing efforts to develop and distribute a malaria vaccine. This dedicated group of individuals, including Treasurer Neil Jones, Secretary Laraine Brennan OAM, and several other committed members, meets quarterly to discuss the latest scientific advancements, strategize on future fundraising initiatives, and ensure the project's continued progress.

During these quarterly meetings, the committee hears updates from key researchers Professor Michael Good AO and Associate Professor Danielle Stanisic from the Institute for Biomedicine and Glycomics. These updates often include significant milestones, such as the initial production of the malaria vaccine and the commencement of Phase I clinical trials. The committee are also kept Informed on the logistical and regulatory aspects necessary to advance the vaccine through subsequent trial phases.

Fundraising is a critical component of the committee's agenda. They brainstorm and plan various fundraising activities, such as dinners, BBQs, golf days, and trivia nights, to support the project's financial needs. The committee's efforts have been instrumental in raising approximately $3 million to date, which has been crucial for the project's development and the sponsorship of postdoctoral scholars to join the research team.

The committee's work is not only about raising funds but also about fostering a sense of community and shared purpose among supporters. They regularly engage with Rotary Clubs and other stakeholders to maintain momentum and enthusiasm for the project. Their quarterly gatherings are a testament to their unwavering commitment to eradicating malaria and improving global health.

FINANCIAL UPDATE

Neil Jones

Since our last report in September 2024, donations have been relatively slow and to date for Financial Year 2024/25 total $27,555. The Rotary Clubs of Scarborough ($5,000) and Cleveland ($4,205) and two individual Rotarian donations (totalling $16,000) were the major contributors.

Total funds raised is moving slowly towards the $3 million milestone and now stands at $$2,941,510.

Source of funds to date is summarised ($000's):

Rotary and Rotary related	$ 849	28.9%
Individual Donors (non Rotarian)	$ 726	24.7%
Government & Government related	$ 550	18.7%
Griffith University Support	$ 522	17.7%
Private Trust	$ 260	8.8%
Corporate	$ 35	1.2%
	$2,942	**100.0%**

The top five Rotary Club contributors (Hope Island, Hornsby, Surfers Paradise, Gold Coast and Mermaid Beach) have jointly donated in excess of a quarter of a million dollars, an extraordinary effort.

Our very sincere thanks go out, not only to those clubs but to each and every donor, large and small. Your contributions have been critical to the project achievements to date and the ultimate success to come.

With the Phase I Trials (fully funded) about to start and in the confident expectation of success, we are turning our focus towards funding the manufacture of the vaccine for the Phase II trials in an endemic country.

Neil Jones
16 March 2025

OPINION PIECE ON MALARIA

Written by Bill Turner

Malaria – an opportunity to make a significant impact on its eradication

Malaria is one of the world's deadliest diseases and is endemic in tropical regions in sub-Saharan Africa, Latin America and Asia. The World Health Organisation reported in its World Malaria Report 2024, that in 2023, there had been 246 million cases and 569,000 deaths in the African Region and that 76% of all deaths in that region had been children aged under 5 years.

For many years now, medical research institutions have been working on developing malaria vaccines for mass drug administration. Some researchers have even been working on genetically modifying the mosquito as a step towards developing a vialled vaccine for subsequent mass drug administration. However, to date, only two vaccines have achieved the approval of the World Health Organisation; the RTS,S vaccine (by GSK and PATH's Malaria Vaccine Initiative supported by the Bill and Melinda Gates Foundation) approved in July 2022, and the R21 vaccine (by Oxford University) approved in December 2023; amazingly recent for such a serious global medical issue.

For the last 10 years, medical research professionals at Griffith University's Institute for Biomedicine and Glycomics (IBG) have been researching malaria and have developed a new vaccine which they call PlasProtecT, which has successfully passed mandatory toxicology assessment and is currently being prepared for evaluation in a Phase I clinical trial. This trial will evaluate a field-deployable version of the PlasProtecT vaccine in malaria-naive human volunteers and will commence in mid-2025, in Melbourne. It is anticipated that following success of the Phase l clinical study, a Phase II clinical trial will be commenced to test the vaccine in one or more endemic countries in Africa.

The PlasProtecT project is led by Professor Michael Good AO, Principal Research Leader at the IBG, supported by Associate Professor Danielle Stanisic, Research Leader and a team of medical-research professionals. Professor Good was asked to provide a simplified outline of the malaria issue and the expected benefits of the PlasProtecT vaccine, which follows:

"When thinking about malaria vaccines, it is very helpful to think in terms of the life cycle of the malaria parasite. Basically, it exists in different forms, in either the mosquito or the human. The parasite enters the human body following the bite of an infected mosquito. Typically, only 5-10 parasites (called sporozoites, microscopic in size) might enter the body, travelling via the blood stream to the liver, where they then enter a liver cell. Here, they multiply extensively over 8 days such that 1 parasite becomes ~30,000 new parasites (now called merozoites, which look different to sporozoites and have different proteins). These then leave the liver and infect red blood cells, where 1 merozoite might become 24 over 48 hours, then bursting out of the red cell to enter new red cells. This exponential growth in red cells is what makes malaria deadly, as it causes anaemia and also cerebral malaria and pulmonary disease. These diseases in the tissues (brain, lung and elsewhere) occur because the infected red cell becomes 'sticky' and does not pass through the tissues, but lines the surface of the small blood vessels, causing them to clog up.

"The two vaccines that have been licensed so far (RTS,S and R21) are both very similar and induce antibodies that attempt to kill the sporozoite form injected by the mosquito. The difficulty with these vaccines is that a very large amount of antibody is required to kill these sporozoites before they enter the liver. The vaccines are ~70 percent effective out to 6 months following the 4-dose vaccine regimen, but this falls off to ~30% after one year, and essentially nothing after that unless the vaccine is re-administered.

"Our vaccine is very different. Firstly, our vaccine does not target the sporozoite stage, but it kills the parasite in the merozoite stage, within the red cells. Secondly, it does not work by inducing antibodies, but by activating T-cells to cause inflammation within the spleen and the

inflammatory molecules of the immune system kill the parasite there. Unlike the RTS,S and R21 vaccines, the immune response to the parasite will increase over time as people are re-exposed to malaria.

"Our vaccine aims to predominantly reduce disease and death from malaria, but does not aim to rapidly eliminate the parasite from the body. The parasite will be eliminated over about 7-10 days, and in that time it will 'boost' the immune response to heighten the response against subsequent malaria attacks. This does not happen with the RTS,S and R21 vaccines because there are simply too few parasites injected by the mosquito to have a meaningful engagement with the immune system.

"We see our vaccine being complementary to RTS,S and R21 because they attack the parasite at different stages of the life cycle. Essentially, the parasites that are not killed by RTS,S or R21 prior to entering the liver will be 'mopped up' by our vaccine during the red blood cells stage of the life cycle. Furthermore, the PlasProtecT vaccine can be produced as a powder, making shipment to remote locations much simpler.

"We believe that our vaccine can be made in-country with training of local health professionals. We are looking for funds to establish the shipping-container model, initially at Griffith University, but then to be rolled out to multiple sites, starting with the most endemic countries (such as DRC, Uganda, Nigeria). This is not a commercial venture for Griffith University and we expect to make no profit from this vaccine.

"This is our big vision, and we would love the mining fraternity to work with us to establish this vision as reality."

In 2014, the Australia-Africa Minerals & Energy Group (AAMEG) was involved in IDRAM (Ebola) Initiative, which was essentially a training program aimed at positioning four copper mining companies in the DRC to be appropriately prepared with early-response capabilities, should an outbreak of Ebola occur in the vicinity of their operations. The program emerged from a meeting at Chatham House, London. The toolkit for the training program had been developed by two NGOs from the USA (FHI 360 and Ecology & Environment) under the Emerging Pandemic Threats Program. The field program was led by InternationalSOS and funded by the United States Agency for International Development (USAID).

Whichever country the Griffith University Phase ll field testing commences in, consideration needs to be given to the DRC being included at some stage, given it has the second highest number of malaria cases and deaths globally. In this regard, it should be noted that since November 2010, through the U.S. President's Malaria Initiative (PMI), the USAID has contributed approximately $650 million in malaria tests, medicines and prevention tools, such as insecticide-treated nets. It would seem very likely that multilateral and other international organisations would be willing supporters of a PlasProtecT Phase ll roll-out in the DRC and other African countries, particularly if the mining sector were also willing to provide its logistical support initially and perhaps financial support in the fullness of time.

Bill Turner

Bill Turner AO is a geologist with over 35 years of international experience in the mining industry. He is a former president & chief executive of Anvil Mining. Mr Turner is also a founding director of the Australia-Africa Minerals & Energy Group ('AAMEG') and was its chair from 2011 to February 2016. He is a Fellow of the Australasian Institute of Mining and Metallurgy and was Chair of Geo40 Limited for almost 12 years. Mr Turner holds a Bachelor of Science (Geology and Mineralogy) from Queensland University, a Master of Science from James Cook University, and an MBA from Monash University.

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

Rotary District 9640

ZARRAFFA'S COFFEE

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