Griffith UNIVERSITY
Institute for Glycomics
Queensland, Australia

Development of a Clinical Phase Malaria Vaccine

A novel whole-parasite, blood-stage vaccine approach to eradicate malaria worldwide.

Background

The protozoal parasite *plasmodium falciparum* is the leading cause of fatal malaria infection and is endemic in nearly 100 countries worldwide. In 2016 there were an estimated 216 million clinical cases of malaria, leading to around 445,000 deaths. Children under 5 years of age account for a large percentage of these fatalities. With some 2.4 billion people at constant risk of infection, primarily in developing countries, an effective vaccine capable of inducing long-lasting immunity is desperately needed.

A number of sub-unit vaccine candidates have been tested in Phase II and III clinical trials but have demonstrated only limited efficacy. An alternative vaccine strategy is to utilise the whole parasite, thereby overcoming many of the deficiencies associated with sub-unit vaccine approaches that have impacted on their success.

The Technology

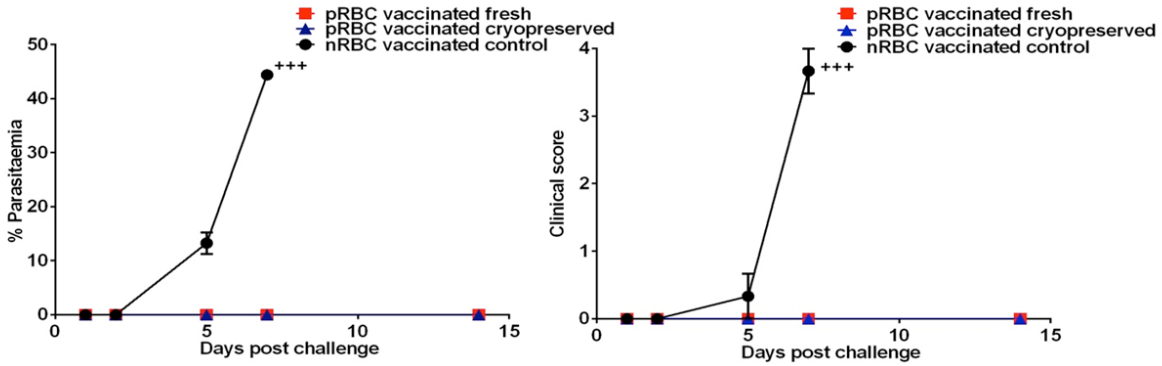
We have developed a whole-parasite, blood-stage vaccine candidate, PlasProtecT™, which utilises a chemical agent (Tafuramycin-A, Tf-A) to attenuate the parasite. We have **demonstrated safety and immunogenicity of PlasProtecT™ in humans** in a pilot study, with parasitised RBCs (pRBCs) derived from *in vitro* culture being used to make the vaccine. A larger Phase I trial with malaria-naïve volunteers is currently being run to determine the efficacy of PlasProtecT™ in protecting against malaria infection.

The human clinical studies have used fresh parasites in the vaccine, which presents challenges downstream for scaled commercial production. We have now manufactured a cryopreserved, purified vaccine product which we believe will mitigate the issues surrounding the fresh vaccine product, allowing for scaled GMP production and distribution to endemic areas.

Global Malaria Vaccine Market

The global malaria market is described by four segments: public, private, traveller and military. Each of these segments have different product profile requirements, particularly relating to efficacy, cost and duration. The vaccine market for global travellers and military in 2025 is estimated at 1.7-3.3 million people and approximately 12.5 million people, respectively. The public vaccine market is estimated to be 70 million people. Reports show that the global malaria vaccines market is valued at US$8.5 million in 2018 and is expected to grow to **approximately US$592 million in 2024**. Significant investment from government and philanthropic sources will allow the vaccine to be distributed to developing nations.

Fighting diseases of global impact



Parasitemia curves and clinical scores in mice immunised with a single dose of attenuated fresh or attenuated cryopreserved ring stage *P. chabaudi* vaccines and challenged with *P. chabaudi*. *P. chabaudi* represents the murine model for malaria infection.

Competitive Advantage

Our whole-parasite, blood-stage vaccine approach presents several advantages over other vaccine candidates.

Firstly, the use of an attenuated whole parasite overcomes the primary issue of antigenic diversity, which is imiting the success of sub-unit vaccine candidates.

Secondly, the method of chemical attenuation provides further scope for adaptability to other malaria parasites including *P. vivax*, which is responsible for approximately 41% of infections outside of Africa.

Finally, as a blood-stage vaccine candidate, PlasProtectT targets the most destructive stage of malaria disease and reduces the severity of infection without the requirement for 100% efficacy (unlike liver-stage vaccines). Potentially, this also allows for enhanced natural immunity to be maintained through boosting in endemic areas.

The most advanced *P. falciparum* vaccine, RTS,S (Mosquirix™), is a liver-stage, sub-unit vaccine. Recent Phase III clinical trials have shown the vaccine provides only 30% protection after four doses. With the WHO recommending protective efficacy of greater than 75%, the industry recognises the need for multiple vaccine candidates to be developed.

Intellectual Property

The technology is covered by patent application WO2012162731A1, which has been granted in Australia, Europe and the USA.

Title: Blood Stage Malaria Vaccine

Partnering Opportunity

This clinical stage malaria vaccine technology is now ready for license to an industry partner dedicated to the global fight against malaria.

RESEARCH LEADER

Professor Michael Good is an internationally recognised leader in the field of immunology and vaccine development. He is the recipient of the National Health and Medical Research Council Australia Fellowship and an Officer of the Order of Australia (AO) for contributions to medical research and education. Professor Good is author of over 300 peer-reviewed publications and is co-inventor of more than 10 patent families.

ABOUT US

The Institute for Glycomics is a flagship biomedical research institute at Griffith University's Gold Coast Campus in Queensland, Australia. The Institute is one of only six of its kind worldwide and has a strategic focus on translating drug and vaccine discovery research into clinical outcomes. We have a strong track record in commercialisation and industry engagement, and our research leaders and business personnel have extensive experience in developing technologies for the commercial market. With over 230 multidisciplinary researchers and support staff, the Institute for Glycomics is well positioned to deliver tangible clinical solutions for infectious diseases and cancer.

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