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PARTICIPANT INFORMATION SHEET: VAC089

A study to assess the safety and effectiveness of two experimental malaria vaccines

We are inviting you to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it would involve. Please take time to read the following information carefully and discuss it with friends, relatives and your General Practitioner (GP/doctor) if you wish.

- **Part 1** tells you the purpose of the study.
- **Part 2** tells you if you are eligible to take part and what will happen if you take part.
- **Part 3** tells you about any possible risks and benefits of taking part.
- **Part 4** tells you more information how the study will be carried out.

Ask us if there is anything that is not clear or if you would like more information. You will be able to discuss the study with us if you attend a screening visit, and we're happy to answer queries before this too. You can contact us using the email address or telephone number at the top of the page. Take time to decide whether or not you wish to take part.

This information booklet has been reviewed by four members of the Jenner Institute's patient and public involvement (PPI) team. The PPI team make sure the information is presented in a way that is understandable to a non-medical/scientific person.

Who can take part?	Healthy adults aged 18-45 (full criteria inside)
What vaccines are being tested?	Malaria vaccines RH5.1 and R78C
Total participants	Approximately 32-36 participants
Study aims	To test safety and immune responses to these vaccines
Trial site	Centre for Clinical Vaccinology and Tropical Medicine (CCVTM), Churchill Hospital, Oxford, OX3 7LE
Expenses and payment	£1,665 to £2,135
Risks of participation	Short-lived post vaccine symptoms such as arm pain and fever may occur. A full discussion of risks, including potential, rare but serious reactions is contained within (page 10). As this is a phase 1 study, we will monitor the safety of all participants closely.
Benefits of participants	Participating in this trial will help our research into the development of a safe and effective vaccine against malaria.
Visit schedule	18 to 23 visits over 12 to 14 months

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PART 1: THE PURPOSE OF THE STUDY

Why are we conducting this study?

Malaria is a major public health problem. It is an infectious disease caused by a parasite which is spread by the bite of an infected mosquito. There were around 240 million cases of malaria and 627,000 deaths worldwide in 2020. Most of the deaths are in children under five living in Africa. It is a major problem for those who live in affected areas and for travellers. There is a great need for a safe, effective malaria vaccine. This is because the range of effective medicines for treating malaria is limited and commonly used medicines are becoming less effective. Researchers around the world, including at the University of Oxford, have been investigating malaria vaccines for many years.

You may have seen news that the World Health Organisation recently recommended one malaria vaccine, known as "RTS,S". This is being given to young children through national vaccination programmes in three African countries. However, this vaccine is not yet widely available and it is also only partially effective. We are trying to make a vaccine that is better than this one at preventing serious illness and death.

This study is being done to evaluate two experimental malaria vaccines for their safety. We will also look at the body's immune response to the vaccines. The vaccines we are testing in this study are called "**R78C**" and "**RH5.1**". They are given with an adjuvant called "**Matrix-M**". An adjuvant is a substance to improve the body's response to a vaccination.

The aim is to use the vaccines and adjuvant to help the body make an immune response against parts of the malaria parasite. This study will assess:

1. The safety of the vaccines in healthy participants.
2. The response of the human immune system to the vaccines.

We will do this by giving participants three or four doses of the vaccines. We will then do blood tests and collect information about any symptoms that occur after vaccination. We aim to recruit 8 or 9 participants to be vaccinated in each of four groups.

What are the vaccines being tested?

RH5.1 and **R78C** are both 'protein vaccines'. Protein vaccines contain small purified protein pieces from the pathogen which have been selected to trigger a strong immune response. Protein vaccines have been used safely for decades.

RH5.1 is based on part of a malaria protein known as RH5. R78C is based on parts of malaria proteins known as RIPR and CyRPA. The malaria parasite uses RH5, RIPR and CyRPA together as a 'key' to get into red blood cells. This is how people get sick from malaria.

RH5.1 has been used in two previous trials and given to over 100 volunteers. It has been shown to be safe and well tolerated in these trials. It has also been shown to help the body make a good immune response and slow down the rate of malaria infection. This was shown in a recent study of healthy UK volunteers who were deliberately infected with malaria to test the vaccine. However, the vaccine ultimately doesn't stop the malaria from getting inside the red blood cells and spreading through the bloodstream; it just slows it down.

R78C has not been given to humans before. However, other malaria vaccines based on similar technology, such as RH5.1, have been given safely to hundreds of people.

Matrix-M has been given to tens of thousands of volunteers in other vaccine trials. It has been shown to be safe and well tolerated. This includes trials of vaccines for malaria, COVID-19 and influenza. Matrix-M has now been approved for use in the UK as part of Novavax's COVID-19 vaccine.

By giving people R78C/Matrix-M and RH5.1/Matrix-M, we hope the body will develop an immune response that is even better than the response seen against RH5.1 in previous studies. The ultimate goal is for a vaccine to help the body prevent the parasite from using the RH5, RIPR and CyRPA 'key' to get into the blood cells and so stop malaria from causing illness.

Do I have to take part?

No. It is up to you to decide whether or not to take part. Your decision not to take part will not result in any penalty, or loss of benefits to which you are otherwise entitled. You are free to withdraw at any time without giving a reason. However, we may ask you to return to the clinic for follow up for safety reasons.

For University of Oxford staff or students: The University does not urge, influence, or encourage you to take part in this research study. Your decision not to participate in the study, or a decision on your part to withdraw from the study, will have no effect whatsoever on your employment or student status at the University.

What will happen if I decide to take part?

This study involves having three or four doses of an experimental malaria vaccine. This may be R78C, RH5.1 or both. You will be followed up with regular clinic visits and blood tests.

Visits will take place at the Centre for Clinical Vaccinology and Tropical Medicine (CCVTM). This is at the Churchill Hospital in Oxford. The CCVTM clinic is wheelchair accessible. You will be asked to complete a diary to record any symptoms you experience after each vaccination.

Length of research

You will be involved in the trial for about 12 to 14 months. There will be 18 to 23 visits (see detailed visit schedule on page 7). Group 3 has an optional extra visit at 20 months but whether you can attend this visit will not affect your eligibility.

PART 2: WHO CAN TAKE PART AND WHAT WILL HAPPEN?

Am I eligible to take part in the trial?

In order to be involved in the study you must be:

- A healthy adult aged between 18 and 45 years.
- Able and willing to meet all study requirements.
- Willing to allow the Investigators to discuss your medical history with your GP (General Practitioner).
- Willing not to donate blood during the study.

You cannot take part in this study if:

- You have had malaria before.
- You have travelled to an area with malaria transmission in the last 6 months. Or, you are intending to travel there during the study period.
- You have previously received a malaria vaccine.
- You have had any other vaccine in the past 30 days or plan to have any other vaccine within 30 days of receiving the study vaccines (apart from COVID-19 vaccination).
- You are taking part in another study using an experimental treatment.
- You have received any other blood products in the last three months. This includes a blood transfusion or immunoglobulins.
- You have problems with your immune system. This includes taking any medication that suppresses your immune system.
- You are pregnant, breast feeding or intend to become pregnant during the study.
- You have a history of allergies or reactions likely to be worsened by any part of the vaccine.
- You have had an anaphylaxis after vaccination.
- You have a history of cancer. 'Basal cell carcinoma' of the skin and 'cervical carcinoma in situ' are not an exclusion.
- You have a history of a serious mental health condition that may affect your taking part in the study.
- You have any other serious long-term illnesses requiring hospital follow-up.
- You drink on average more than 25 units of alcohol a week. A pint of beer is two units, a small glass of wine 1 unit and a shot of spirits one unit.
- You have injected recreational drugs at any time in the last 5 years.
- You have hepatitis B, hepatitis C or HIV infection.
- There are any other reasons that the study doctors think you should not join the study.

Mild conditions would not automatically exclude you from taking part. An example could be childhood asthma, which is well controlled. If you are unclear whether you are eligible to be involved in the study you can contact the study team who will be able to advise you.

Is there anything else to think about?

Blood Donation

Under current UK regulations, volunteers will not be able to donate blood during the study.

Pregnancy and Contraception

The potential effect of the vaccines used in this study on an unborn baby is unknown. If you are able to become pregnant then you will be asked to use an effective method of contraception until at least 3 months after your final vaccination. This will be approximately a total of 9 months for Groups 1 and 2, and 10 months for 4. For Group 3 it will be approximately 5 months. Condoms alone are not considered effective enough.

Acceptable forms of contraception include:

- Established use of hormonal contraceptives. This includes the pill, mini-pill, contraceptive injection or implant.
- Placement of an intrauterine device or intrauterine system. These are also known as the copper coil or hormone coil (e.g. Mirena coil).
- Vasectomy (male sterilisation), if this is your only partner.
- Complete abstinence from any sexual relationships in which you may become pregnant. Periodic abstinence and withdrawal methods are not acceptable.

A pregnancy test will be done at screening and just before each study vaccination.

Private Insurance
If you have private medical insurance you should contact your insurance company before participating in this trial. Involvement may affect the cover provided.

Malaria Protection
You should not assume that the experimental vaccines you receive in this study will give you any protection against malaria. Make sure you visit your GP or a travel clinic before travelling to an area where malaria is found. You should follow their advice on prevention measures.

What will happen at the visits?

Screening Visit
First we will need to check whether you are eligible to join the study. Following an online pre-screening questionnaire we will contact you by telephone or email. You will have an opportunity to ask any more questions about the study at this point. We will also arrange for you to attend a screening appointment.

The screening appointment takes place up to 3 months before the study starts. It can last up to two hours with an opportunity for a short break. The purpose of the screening visit is for you to discuss the trial with us and decide if you still wish to take part. If you do, we will ask you to sign a consent form.

After signing the consent form:
- You will be asked some medical questions.
- A doctor will examine you.
- Blood samples and a urine sample will be taken for testing. These test results will need to be normal for you to be enrolled in the study.
- If you are able to become pregnant then you will have a urine pregnancy test.

The blood tests will look at:
- Your blood count (for example, to check if you are anaemic).
- Your liver and kidney function.
- Whether you have hepatitis B, hepatitis C or HIV. This is because these conditions can affect your body's response to the vaccines we are assessing.

If any of your test results are not normal, we will let you know and arrange for a repeat test. With your consent we may also report any abnormal results to your GP and offer to refer you for further investigation/treatment.

Some individuals may test positive for Hepatitis C virus due to previously taking part in a Hepatitis C vaccine study. If this applies to you and you wish to take part in our study, with your written consent, we will contact the team responsible for the Hepatitis C vaccine study. We will check your Hepatitis C status with them before enrolling you in this malaria vaccine study.

Vaccination visits
The table below shows each group and the vaccinations they will receive. Each vaccination will be given together with the Matrix-M adjuvant. The study doctor will talk to you about which group you would be enrolled in. This will depend on when you enrol in the study and so you will not be able to choose which group you are in.

Group	Vaccine on day 0	Vaccine on day 28	Vaccine on day 56	Vaccine on day 182	Vaccine on day 210
1	R78C	R78C		R78C	
2	R78C + RH5.1	R78C + RH5.1		R78C + RH5.1	
3	RH5.1	RH5.1	RH5.1		
4	R78C + RH5.1	R78C + RH5.1		R78C	RH5.1

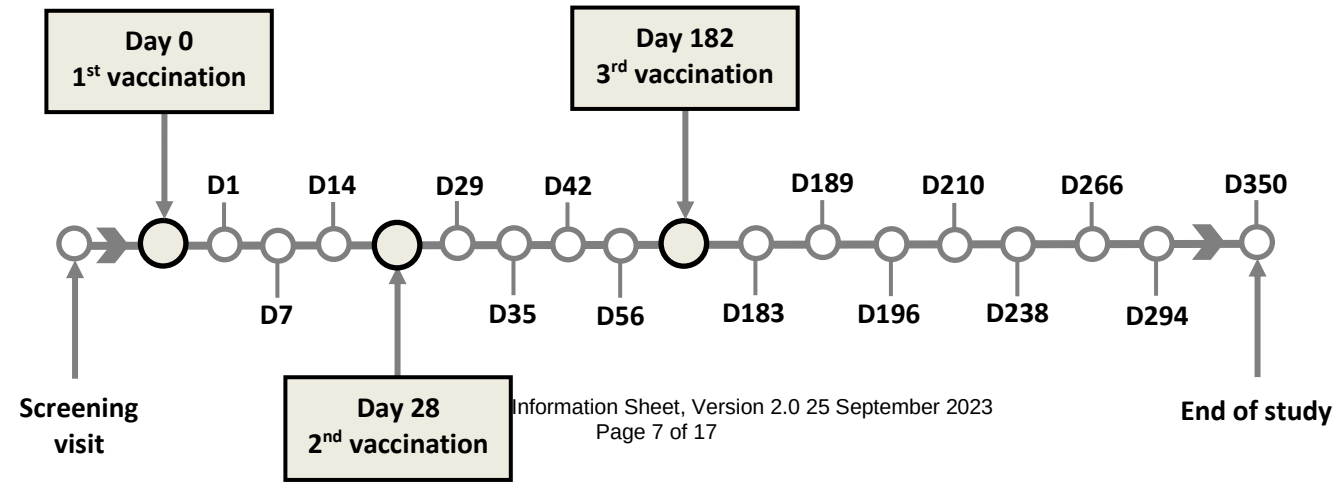
Vaccinations will be given into the muscle of the upper arm (alternating for each vaccination). We will ask you to wait for 60 minutes after each vaccination to check there are no immediate problems. You will be given a thermometer and tape measure to take away. We will also show you how to use the electronic diary. There will also be a paper diary available if you are unable to use the electronic diary. We will ask you to record your symptoms and measure any redness at the vaccination site every day for 7 days after each vaccination. After the first 7 days, we will ask you to record if you feel unwell or take any medications over the next 3 weeks.

We may ask to photograph your vaccination site. You can choose whether or not to agree to this when you sign the consent form. Your face will not appear in any such photographs. Only the vaccination site and your unique trial number will be visible. These photographs may be shown to other professional staff, used for educational purposes or included in a scientific publication.

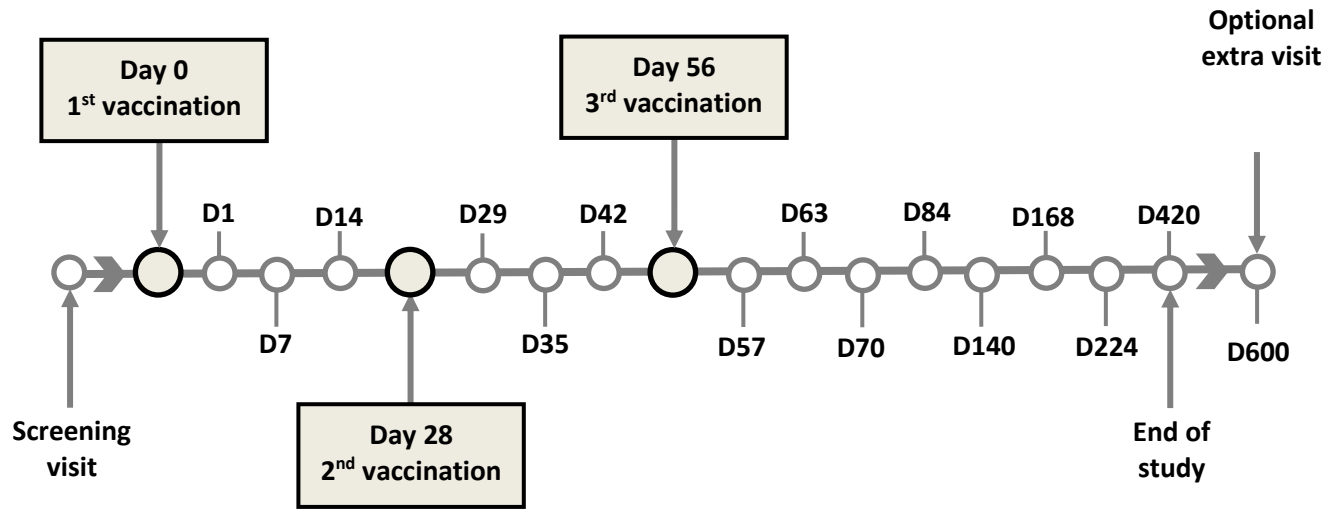
Follow-up visits
The diagram below shows the timing of post vaccination follow-up visits. Visits include a medical assessment and examination by a doctor if needed. We will also take temperature, pulse and blood pressure readings as well as blood tests.

Schedule of Visits: Circles denote in-person clinic visits

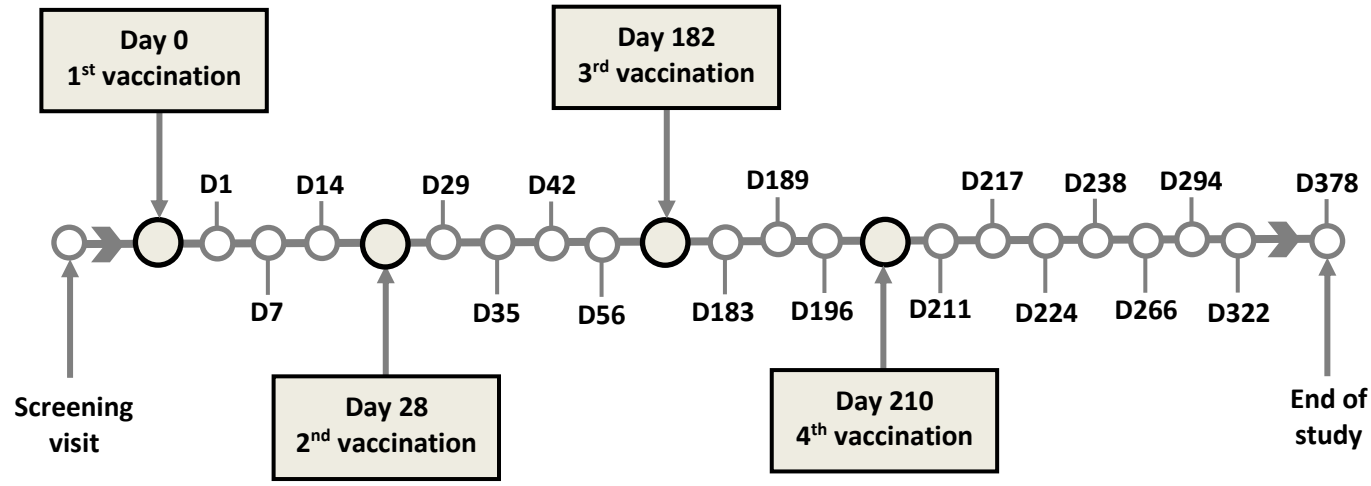
<u>Groups 1 and 2</u>



Group 3



Group 4



Expenses and payments

You will be compensated for:

- Screening visit £75
- Travel expenses (enrolled volunteers): £30 per visit (if travel to the trial site costs more than £30 additional reimbursement may be offered)
- Time required for visit (enrolled volunteers): £40 per hour
- Inconvenience of blood tests: £20 per blood donation
- Extra visits (if required): £90 per visit

The overall compensation will be between £1,665 to £2,135 depending on your study group, as shown in the table below. If you choose to leave the study early, or are withdrawn, you will be compensated according to the length of your participation. This will be calculated based on the figures above. **Compensation payments received in this trial may have an impact on your entitlement to benefits.**

Group No.	Time in Trial (approx.)	No. of Clinic Visits	Compensation Amount
1-2	12 months	19	£1,755
3	14 months (with optional 20 month visit)	18 (+1 optional visit)	£1,665 (+£90 for optional visit)
4	12 months	23	£,2,135

What do I have to do?

- You **must** attend all the visits that are outlined above.
- If you are able to become pregnant you **must** use effective contraception until 3 months after your final study vaccination.
- You **must not** donate blood during the study.

PART 3: RISKS AND BENEFITS

What are the risks of taking part?

The potential risks are as follows.

Blood Tests

The total volume of blood taken during the study depends on the group. The amount taken at each visit will vary between around 3ml (less than a teaspoon) to a maximum of 80 ml (less than 6 tablespoons). The volume of blood being taken over the course of the trial should not cause any problems in healthy people. There may be some temporary mild discomfort. This may include bruising and tenderness at the site where the blood is taken. You may feel faint as a result of collecting blood.

We will give you a copy of your blood test results if you ask for them. We will only send the results to your GP if you wish us to and will not report them to anyone without your permission.

If abnormal results or undiagnosed conditions are found in the course of the study these will be discussed with you. If you agree, your GP will also be informed. For example, a new diagnosis of anaemia might be made. Any newly diagnosed conditions will be looked after by your GP within the NHS.

At different time points throughout the trial, we will take blood samples for the following tests:

- Your blood counts, liver and kidney function
- Blood borne infections (HIV, hepatitis B & C)
- Genetic analysis of your cells (to look at patterns of genes that can affect the immune system) and the parasites
- Immune responses to vaccination. This may include production of specific antibodies called monoclonal antibodies

Vaccination Side Effects

Once the vaccinations have been given they cannot be undone. It is therefore important you understand the potential risks of the vaccines before you join the study.

R78C with Matrix-M has not been used in humans before. However, as a standard part of vaccine development, we have tested R78C with Matrix-M safely on mice.

We do not expect the side effects of this vaccine to be very different from similar vaccines. This includes RH5.1 with Matrix-M. The most common side effects experienced by volunteers who have received RH5.1 with Matrix-M are described below.

We expect that most symptoms will be mild. However, some may be moderate or severe. Symptoms should last no more than a few days.

You may experience any of the following side effects:

- Injection site pain. This is most likely mild. However, there is a chance this could be moderate or severe in intensity.
- Redness, swelling, itching and warmth at the vaccine site. Symptoms are likely to be mild if present. However, there is a chance this could be moderate or severe in intensity.
- A ‘flu-like’ illness within 24 hours of vaccination that usually resolves within 48 hours. This can include headache, muscle aches, joint aches, feverishness, tiredness, nausea and feeling generally unwell. The majority of general symptoms are likely to be mild. There is a small possibility of moderate or severe symptoms occurring.

It is important to remember R78C is being tested in humans for the first time in this trial. This means there is a chance you could experience a side effect different in nature, or more severe than those described.

As this is first time that R78C is being used in humans, we will stagger the recruitment for volunteers in groups receiving this vaccine. This means Group 1 will be recruited first, followed by Group 2 and then Group 4. A safety committee who are independent of the study will meet on four occasions during this time. The committee will review the symptoms that volunteers experience and give us approval for vaccinations to continue. If there are any concerns at this or any other time that side effects are different or more severe than expected then we will pause the trial whilst this is investigated and only continue once we have resolved any concerns.

Severe Reactions

With any vaccination there is a low risk of serious reactions. These may be related to the nervous system or the immune system.

Severe allergic reactions to vaccines (anaphylaxis) are very rare but can be fatal if not immediately treated. Therefore, we will have doctors qualified in the management of anaphylaxis at each vaccination. Appropriate equipment and medication will also be present.

Reactions in the nervous system are also extremely rare. However, vaccines can cause an illness called Guillain-Barré syndrome. This is an illness in which people can develop severe weakness. It may be fatal. However, these reactions have not previously been seen with the type of vaccine used in this study.

If you experience unexpected symptoms, or become in any way concerned you should contact one of the study doctors. Study doctors are available 24 hours a day. We will give you emergency contact details when you attend the vaccination visit.

Taking part in a vaccine study during the COVID-19 pandemic

We now have over 2 years' experience conducting trials during the COVID-19 pandemic. We have developed procedures to keep our volunteers safe and trials running. As the public health situation evolves, we may change some of these procedures, in line with the most up-to-date guidance from the UK Health Security Agency (UKHSA) and the UK Government. If you volunteer, we can discuss the up-to-date policy and volunteer requirements with you when you visit.

Of note, the results of any COVID-19 swab tests done as part of this study must be passed on to UKHSA. This includes tests that are negative. This is because COVID-19 is a 'notifiable disease' and this is a legal requirement.

If you are self-isolating when you are due to attend a clinic visit, please let us know. We will try to re-schedule clinic visits to another time.

To minimise the number of people in the building during study visits, we will give you a specific appointment time for all study visits. You must attend then. If you arrive before your appointment time, please wait outside of the building.

Clinic visits

- Churchill Hospital has policies in place for social distancing measures and face mask use. These are updated regularly. We will let you know what the current policies are. Both study staff and participants will need to follow these policies.

- There may be certain circumstances in which you are advised not to attend clinic. We will let you know what the current policy is.

Vaccinations

- Fever can occur within the first few days following malaria vaccinations.
- If you continue to have a fever after 48 hours following vaccination, then this is less likely to be due to the vaccination. You may be advised to follow current government COVID-19 guidelines for suspected COVID-19 infection.

COVID-19 vaccination

- Please inform us if you have an appointment for COVID-19 vaccination during the trial. You will be able to receive a COVID-19 vaccination if it is given at least 14 days before or 7 days after any malaria trial vaccinations. The malaria vaccinations can be fitted around any COVID-19 vaccination.

There may be other risks, or side effects, which are unknown at this time.

What are the possible benefits of taking part?

This study will not benefit you. The information gained from the trial might help to prevent malaria infection and disease in those who live in areas where malaria is common and in travellers. There are other malaria vaccines in various stages of development.

PART 4: OTHER INFORMATION ABOUT THE STUDY

What if relevant new information becomes available?

Sometimes during the course of a research project, new information becomes available. If this happens, we will tell you about it. We will discuss whether you want to or should continue in the study. If you decide to continue in the study, you will be asked to sign an updated consent form. On receiving new information, we might consider it to be in your best interests to withdraw you from the study. Your participation in this study may also be stopped at any time by the study doctor or the Sponsor without your consent for other reasons.

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time without giving a reason. This will not result in any penalty, or loss of benefits to which you are otherwise entitled. Your data collected and blood samples taken will continue to be used unless you state otherwise. You may request that your blood samples and research data are destroyed at any time during or after the study, although once the study data is fully anonymised it will not be possible to withdraw this.

Your compensation would be paid as a proportion of the total compensation according to the length of your participation.

What if there is a problem?

If you are harmed as a result of taking part in this study, the study doctor can advise you of further action. If necessary, they will refer you to a doctor within the NHS for treatment. The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this trial.

The Investigators recognise the important contribution that volunteers make to medical research. They make every effort to ensure your safety and well-being. In the event of harm being suffered, while the University will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint.

Complaints procedure

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact your local trial team (contact details at the end of this document). You may also contact the University of Oxford, Research Governance, Ethics and Assurance (RGEA) office on 01865 616480 or the head of RGEA, email RGEA.Sponsor@admin.ox.ac.uk

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be coded with a study number and kept confidential. Personal details will be stored securely and separately from the research data.

Responsible members of the University, independent monitors and the regulatory authorities may be given access to data for monitoring and/or audit of the study. This is to ensure that the research is complying with applicable regulations.

With the exception of COVID-19 tests, any information about you that leaves the clinic will have your name and address removed so that you cannot be identified from it. Your information is stored electronically on a secure server. Any paper notes are kept in a locked filing cabinet.

Involvement of the General Practitioner/Family doctor (GP)

In order to enrol into this study, you will be required to sign a form to say that you consent for us to contact your GP. This is to inform them that you are interested in being involved in the study. We will also check there are no medical reasons that they are aware of that would make your taking part inadvisable. Your GP may be asked to share information about your medical history and give access to any other medical records as needed. The researchers will not enrol you in the trial if they have concerns about your eligibility or safety. We will write to your GP to let them know whether or not you are enrolled in the study. We will also write to let them know whether or not you completed the study, so they can update your medical records accordingly.

Prevention of 'Over Volunteering'

Volunteers taking part in this study must not be receiving investigational medications or vaccines in another study at the same time. In order to check this, you will be asked to provide your National Insurance or Passport number. This will be entered on to a national database which helps prevent volunteers from taking part in too many clinical trials. More information can be found at *www.tops.org.uk*. Your national insurance or passport number is also required to allow processing of compensation payments.

What will happen to any research samples I give?

The results of any COVID-19 swab tests done as part of this study must be passed on to UKHSA. This includes tests that are negative. We will pass on your details (name, date of birth, contact details, ethnicity, NHS number) and date of diagnosis and symptom onset if applicable. This is because COVID-19 is a 'notifiable disease' and this is a legal requirement.

Your study visit blood tests will be analysed in Oxford University research laboratories. Blood tests for your general health will be carried out in the NHS laboratories at Oxford University Hospitals. Some cells from your blood may be used to produce specific antibodies ('monoclonal antibodies'), which could be used for commercial activity in the future. Other blood tests to look at the response of your body to the vaccine will be done with collaborating laboratories in the UK and in other countries. Any samples or data sent to NHS laboratories or collaborating labs will be assigned a study code, rather than your name/personal details (pseudo-anonymised).

If you consent, some of your leftover blood samples will be stored indefinitely at the University of Oxford. This will be coded with a study number. Your personal details will also be stored securely and separately from the research data and sample itself until the samples have been depleted or destroyed in order to comply with the Human Tissue Act. The blood samples may be used for further related research, including of the human body's immune response and/or vaccine research. Any such future research will have an appropriate ethical review. You may request that remaining blood samples are destroyed at any time. If you decide not to consent to storage of your leftover samples, they will be disposed of at the end of the study. Taking part in this study will not be affected by your decision whether to allow storage and future use of your leftover blood samples.

Urine samples will be destroyed immediately after testing.

Will any genetic tests be done?

Yes. Some blood may be used to look at the pattern of your genes that can affect the immune system, so-called "gene expression". As these tests are not done to look at your health we would not give you these test results.

What will happen to my data?

Data protection regulations require that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford, as sponsor, is the data controller. This means that we, as University of Oxford researchers, are responsible for looking after your information and using it properly.

We will use information from you and your medical records in order to undertake this study. We will use the minimum personally-identifiable information possible. The University of Oxford will keep identifiable information from participants collected during the study initially for 5 years after the study has finished. Once the study has been completed, all documents would be archived in a secure facility. In addition, we will securely store the pseudo-anonymised research data and any research documents with personal information, such as consent forms, initially for 5 years after the end of the study. The need to store this information for longer, in relation to licensing of the vaccine will be reviewed every 5 years. Files will be confidentially destroyed when storage is no longer required. For effective vaccines that may be licensed, secure storage of research data may be required for at least 15 years after the end of the study, subject to changes in clinical trials regulations. In addition to the scientific data, we will also store documents containing personal information that you provide when registering for the trial (including contact details), medical information and signed consent forms during this archiving period.

The study team will use your name and contact details to contact you about the research study. We will also make sure that relevant information about the study is recorded for your care, in relation to your health during the study and to oversee the quality of the study. At the end of the study, unless you consent otherwise, your personal details will not be used to contact you other than for exceptional circumstances concerning your safety. If you consent to take part in another study at CCVTM, personal information and medical information including blood test results may be accessed to avoid unnecessary repetition.

Your information may also be shared with partners working with Oxford University. This information will be identified only by the unique trial number and you will not be personally identifiable. All data received will be kept securely by these parties in line with all regulatory requirements. If the study is paused due to safety concerns relating to the vaccine, the local ethics committee and the manufacturers of the vaccine adjuvant (Novavax) will be informed. The data shared would be de-identified.

Your bank details will be stored for 7 years in line with university financial policy.

If you test positive for the hepatitis C virus due to previous involvement in a hepatitis C vaccine study, with your written consent, we will contact the team responsible for the hepatitis C vaccine study as described previously. A copy of this consent will be held by both ourselves and the team responsible for the hepatitis C vaccine study. They will hold your form in the same way they described when you originally joined the study.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at: https://compliance.web.ox.ac.uk/individual-rights

Involvement of Appledown Clinical Research Ltd (ACR)

ACR are independent external monitors used in this study to ensure we are complying with the clinical trial regulations. They will conduct a site visit to prepare and set up the clinical trial prior to recruitment as well as conduct monitoring visits to check the information in source documents (e.g. blood test results and GP

letters). In most documents you will only be identified by a study ID number but they will see some documents which would identify you (e.g. the consent form). They will not retain any data which could identify you personally. For remote monitoring to occur they may require secure online access to electronic documents but will not download or copy them. ACR will comply with the University's Information Security Policies, which are documented in the agreement with the University.

What happens when the research study stops?

If you have any queries or concerns once the study is over, please do not hesitate to get in touch with us.

The data we collect in this study will be shared with the funder (OptiMalVax). It may be made open to the public so that others can learn from it. If data are shared publicly, they will not be linked to you personally.

The results of this research study may be presented at scientific meetings or conferences and published in a scientific medical journal. This may not happen until 1 or 2 years after the study is completed. A summary of the study will also be written for a non-scientific audience and published on the Jenner Institute website (https://www.jenner.ac.uk/). If you contact the researchers in the future, you can obtain a copy of the results. You will not be identified in any report or publication.

The anonymised data from this study will be shared with the partners who are organising and funding this research work. Data from this study may be used to file patents, licence vaccines in the future or make profits in other ways. You will not be paid for any part of this. Data from this study may be used as part of a student post-graduate degree, for example a MD or PhD.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Taking part in future vaccine related research

With your consent, we would like to keep your contact details after your participation in this study is complete. This is so we may inform you of opportunities to take part in future vaccine related research. This is entirely optional. Taking part in this study will not be affected by your decision whether to allow storage of your contact details beyond your participation in this trial.

Your details will be stored electronically on a secure server. Only authorised individuals at the CCVTM will have access to it. We will not, under any circumstances, share your contact details with any third party institutions without your permission. Being contacted does not oblige you to agree to take part in future research. You can ask us to have your contact details removed from our database at any time.

Who is sponsoring, organising and funding the research?

The study is organised by the University of Oxford. The study is funded by OptiMalVax, OptiMalVax is a Collaborative Project on malaria vaccine development funded by the European Union's Horizon 2020 Programme and coordinated by the Jenner Institute at the University of Oxford. Additional financial support for this study will be funded by internal funding from Department of Biochemistry from the University of Oxford. Neither your GP nor the researchers are paid for recruiting you into this study.

The Senior Laboratory Investigator, Professor Simon Draper, is a named inventor on patents for RH5-based and R78C vaccines used in this study and is a founding shareholder in a company developing technology used in these vaccines. The Chief Investigator, Dr Angela Minassian, has a family member

who is an inventor on patents for RH5-based and R78C vaccines and who is a founding shareholder in a company developing technology used in these vaccines. While both Dr Minassian and Professor Draper therefore have a potential conflict of interest, the integrity of the trial is maintained by samples being analysed by non-clinical researchers who cannot link them to individuals (thereby ensuring no bias), as well as the monitoring of safety by an independent Data Safety Monitoring Committee.

Who has reviewed the study?

This study has been reviewed by the National Research Ethics Service Committee [London-Harrow] and has been given a favourable ethical opinion. A Research Ethics Committee is an independent group of people who review research to protect participants' interests.

Thank you for reading this information sheet. If you are interested in taking part in the study please contact the study team at your local study site to arrange a screening appointment.

Contact details for further information:

Volunteer Recruitment Co-ordinator
E-mail: vaccinetrials@ndm.ox.ac.uk
Tel: 01865 611424
CCVTM, Churchill Hospital, Old Road, Headington, Oxford, OX3 7LE