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RATIONALE-15

caRriage to Assess proTectIon Of New pneumococcAL vaccinEs – **PCV15**

Participant Information Sheet – Main Study

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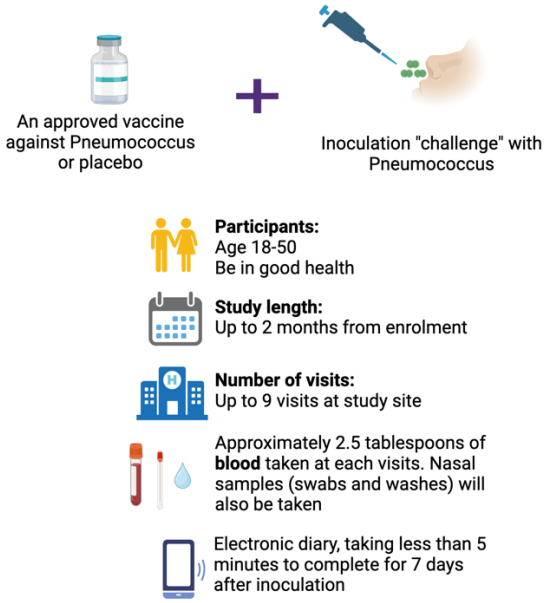
Study Overview

In this study we want to test if an approved vaccine against a bacterium called pneumococcus protects against carriage of pneumococcus in the nose. To test the vaccine, we will use a "challenge" model in which we will put some drops of the pneumococcus bacteria in participant's nose. This is safe and proven to be helpful to study vaccines.



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What is this research study about?

You are invited to take part in a research project sponsored by the University of Oxford and carried out at the Oxford Vaccine Group.

We aim to recruit up to **106 people aged 18-50 years** to take part in a study of an approved vaccine against a common bacterium called *Streptococcus pneumoniae* (Spn, pneumococcus) and test it using a human challenge model to evaluate its effect on carriage. The vaccine is called Pneumococcal Conjugate Vaccine 15, PCV15 (VAXNEUVANCE™).

You can find pneumococcus in the nose of approx. 1 in 10 healthy adults and children. This harmless state is called "carriage"; and people that have it are just carriers of it, often with no symptoms. However, the bacteria can transmit from a person that is a carrier to other people at risk (the elderly, children and people with certain health conditions) and can cause disease (e.g. pneumonia).

In this study we want to understand the immune responses in the nose and blood to PCV15. To do this, we will deliberately expose volunteers to the pneumococcal bacteria in a controlled way and test if the vaccine reduces carriage, therefore preventing transmission to others and infections.

Deliberately exposing volunteers to the pneumococcal bacteria is called Controlled Human Infection. The controlled human infection model with pneumococcus has been tested in over 2000 research volunteers and it has proven to be safe and effective in studying immune responses to these bacteria. Volunteers that become carriers (the bacteria stay in their nose) are treated with antibiotics to reduce/eliminate the carriage.

Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. If anything is not clear or if you would like more information.

Take time to decide whether you wish to take part. Please feel free to consult your doctor or other allied health care professionals if you wish to.

Who are we?

We are researchers at The University of Oxford (https://www.ovg.ox.ac.uk/) and The Liverpool School of Tropical Medicine (LSTM, https://www.lstmed.ac.uk/LVG). We have been studying lung infections using healthy volunteers for over ten years to provide world-leading research into pneumococcus using a method called the Controlled Human Infection Model (CHIM). More than 2000 participants have already been safely studied using this model and we have tested pneumococcal vaccines using this model. Our research is world-leading and we seek to help develop and improve vaccines against pneumococcus and other infections. We have a large amount of experience in running clinical studies and trials like this.

Why is this research study needed?

Pneumococcus causes serious infections such as pneumonia, meningitis and sepsis (severe infection causing inflammation and organ damage) worldwide. The burden of pneumococcal infection is high in low- and middle-income countries with over 1million deaths per year. Even though there are antibiotics to treat pneumococcus, vaccination remains the primary method for reducing its impact.

Small numbers of pneumococcus are often found in the nose, and approximately 10% of the population carry the bacteria at any one time, which is called nasal carriage. It is more common in children, and usually, the carrier is not aware of it and does not have any symptoms. There is some evidence suggesting nasal carriage triggers your immune system and protects you from future disease.

However, young children, older adults and people with chronic illness are at increased risk of developing an infection after carriage, such as pneumonia, meningitis, or sepsis.

Our long-term goal is to help develop more protective vaccines against pneumococcus. To do that, we need to gain a better understanding of how pneumococcus behaves and how current vaccines work. There are over 100 different types (also known as 'serotypes') of pneumococcus, and some of the current vaccines protect against 13 (PCV13 vaccine) and 15 (PCV15 vaccine) serotypes. We are interested in a specific serotype of pneumococcus, serotype 3 (Spn3). This is because although it is included in all those vaccines, it continues to be found in the community, causing infections, particularly in young children and the elderly. We are also interested in PCV15 vaccine, a vaccine that is routinely given to babies and that can potentially protect better against this Spn3 serotype of pneumococcus.

To try to understand how vaccines work and how we can improve them, we want to study the body's immune response to PCV15 and see the effect of the vaccine on the carriage of Spn3. In this study, we will use our human challenge model to assess whether healthy adults are protected against Spn3 carriage after vaccination.

What is the human challenge model and what is the vaccine?

A human challenge model is when we experimentally put a small amount of liquid in your nose containing a known bacteria in a procedure called **inoculation or challenge**, and then we follow how your body responds to it. These models are used for research in many types of infection. We have a lot of experience with Spn challenge studies.

As your safety is our priority, we will make sure that it is safe for you to be part of the study. The Spn3 serotype used in this study can be treated with antibiotics and has previously been safely tested in 60 healthy participants with no safety concerns.

Inoculations carry some risk as the bacteria are alive, and there is a risk of infection to you or your close contacts. Pneumococcal infections can be mild or potentially severe, but usually participants have no symptoms at all. So far, we have not had any severe pneumococcal infections (e.g. participants requiring hospitalisation, injected antibiotics or developing

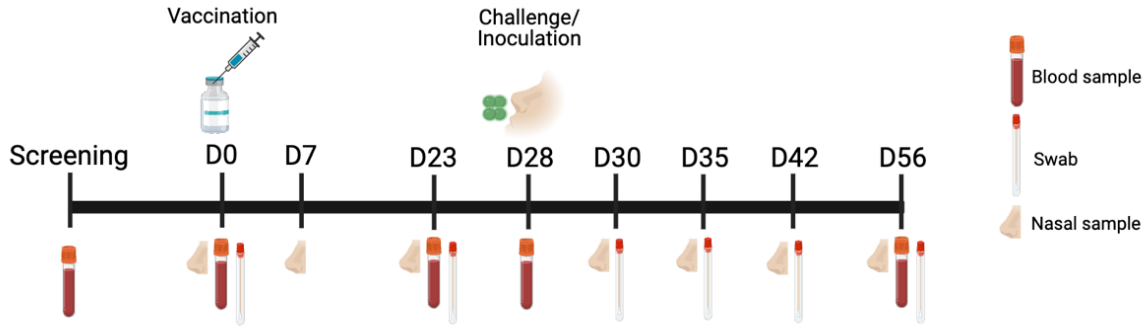
pneumonia) in our trials, having inoculated over 2000 volunteers with several serotypes. You might develop a cough, sore throat, fever or temperature. If that happens, the team will be on hand to determine if this is coincidental or related to the pneumococcus and treatment will be available. Once again, it is worth noting that pneumococcus is commonly found in the nose without causing any problems.

The PCV15 **vaccine** is approved and is currently used in the United Kingdom and many other high- and middle-income countries. The PCV15 market name is VAXNEUVANCE™. It is an effective vaccine against infections from pneumococcus but more data is needed to understand its protection against carriage, specifically Spn3. In this study, we will also use a placebo. The **placebo** consists of a saline solution, given in the same amount and by the same procedure as for the vaccine, you will not know whether you receive the vaccine or placebo until the end of the study, this is called blinding. To maintain blinding in the study, lab staff processing your samples and clinical staff reviewing your safety will also remain blinded.

More information about how vaccines are made is available at https://vaccineknowledge.ox.ac.uk/vaccine-ingredients

What will happen in the study?

All participants will have 1 dose of the PCV15 vaccine or placebo and will receive the challenge with Spn3 1 month after. The total duration of the study is approximately 2 months from vaccination. See study timeline below:



We are looking for healthy adults aged 18-50 years to take part. People with serious medical conditions, immune system conditions (the study team will discuss with you examples of such conditions) or people that care for people with these conditions and children younger than 5 years old will not be able to take part. People that have been vaccinated with a pneumococcal vaccine in the past 5 years or that took part in a human challenge study with Spn in the past 2 years are not eligible as well. We will also exclude participants that have allergy to amoxicillin as we may use this antibiotic to clear pneumococcal carriage at the end of the study and if indicated by the study team.

If you are unsure whether you can join the study, you can contact the study team to discuss further. The criteria are available on the online screening questionnaire and will be discussed at the screening visit.

- **Online Screening Questionnaire:** https://www.ovg.ox.ac.uk/studies/rationale15 to check if you can take part by asking about your medical history and record your contact details. This registers your interest in the study and we will ask you to provide your NHS number and consent for the study team to access your medical records through your GP and other NHS databases and record your contact details. Your contact details will be kept secure and confidential (for more information please refer to the confidentiality section below).
- **Screening visit:** You will discuss the study with a member of the clinical team, and you can ask any questions. You will be asked to complete a short quiz, to check your understanding of the study and to make sure the research staff tell you everything you need to know. If you wish to take part, you will be asked to sign a consent form.

Our research staff will confirm your medical and vaccine history, perform a physical examination, check your vital signs, and take blood and nasal samples, and a urine pregnancy test (if applicable). You will need to provide proof of National Insurance Number (UK citizen) or Passport (non-UK citizen) for the team to register you on The Over-volunteering Prevention System (TOPS). This is performed as standard practice when volunteering in a research study and acts as a safety measure to prevent volunteers taking part in multiple studies that when

combined, may negatively impact their health due to drug interactions or having to provide multiple blood samples. When all the results are available following your screening appointment, the research doctors will assess and confirm if you are eligible to take part in the study. This visit will take around 1 hour and a half and will occur at your local study site.

- **Group allocation:** If eligible, you will be randomised by computer software and allocated to either the group having the PCV15 vaccine or the placebo. This is like flipping a coin, the clinical team cannot influence which group you are allocated to.
- **Vaccination visit:** You will be asked about any changes in health since your screening visit, check your vital signs and collect a blood and nasal samples. If appropriate you will have a urine pregnancy test before the vaccination. The PCV15 vaccine or the placebo will preferably be given as an injection into the muscle of your non-dominant arm. The site of the injection may be covered temporarily, and you will be observed for at least 15 minutes to observe for any reactions. This visit will take around 1 hour and a half and will occur at your local study site.
- **The vaccine dose** contains components of 15 serotypes of pneumococcus attached to a protein that improves the immunity generated by the vaccine. Expected symptoms or reactions and possible reactions seen with similar vaccines will be discussed in the section **vaccination related risks**.
- **Challenge visit:** This visit will take around 1 hour and a half and will occur at your local study site. You will be asked about any changes in health since your screening visit, check your vital signs and collect blood and nasal samples. We ask you to lie relatively flat and then put a small amount of liquid containing the bacteria in your nose using a pipette. This procedure does not cause any discomfort, but it might tickle your nose and make your eyes water. You might feel some liquid trickle down the back of your throat. You will be observed for 15 minutes for any reaction. We will provide you with a safety pack to keep with you throughout the study, this includes:
    - Course of antibiotics to keep with you in case you are unwell
    - Thermometer to check your temperature at home
    - Safety information sheet
    - Study contact card (with the information for you to contact one of the study doctors if you are concerned)

- **Electronic symptom diary (eDiary):** At the challenge visit you will be given access to an online symptom diary. We will request your email address to set up your eDiary and send you the daily links to the eDiary and reminders. We will ask you to record any symptoms and illnesses you experience in the 7 days following inoculation, even if you think they are not related. For the first 5 days we will ask you to record your temperature each morning using an oral thermometer that we will give you and update it into your diary. We ask that you reach out to the team with your temperature recording for the first 5 days before 12noon. We ask for the diary to be completed before 1200h every day. The study team will explain to you how to complete the eDiary and you can contact the team in case of having issues completing. We will also provide a paper back-up diary and explain how to use it.
- **Follow-up visits:** After the inoculation you will attend the clinic for several short follow-up visits. At these visits we will ask about any symptoms or illnesses that you have experienced, review your eDiary and take blood, throat swabs and nasal samples. The amount of blood taken can vary according to when the visit is taking place. Approximately 60 mls, (which is about 4 tablespoons) of blood is taken at certain in-person visits (approximately 15 tablespoon in total for the study). For comparison, a single donation to the NHS blood bank would be approximately 470ml. The blood is taken to assess the immune responses of the participants to PCV15 and challenge. We may need to repeat blood tests if anything needs checking. These visits will take around 1 hour and will occur at your local study site.
- ***Nasal Biopsy Cohort:*** A small number of volunteers will be invited to take part in a subgroup of the study where the vaccine is given, and 2 nasal biopsies are taken. These volunteers will not be challenged with pneumococcal bacteria and will have fewer clinical visits. Further information is available https://www.ovg.ox.ac.uk/studies/rationale15. If you are interested in taking part in this cohort, please inform a member of the study team.

Are there any risks in taking part in this research?

Vaccine related

PCV15 is a licensed vaccine in the United Kingdom. There is no risk of developing pneumococcal pneumonia or other pneumococcal infection from the vaccine. This vaccine is part of the immunisation programme against pneumococcal disease for children and adults at risk. We will give the vaccine in the same way it is given to babies and older adults routinely.

Side effects of the vaccine are as you would expect to see after any vaccine and includes pain, redness, swelling and itchiness at the site of the injection. These are temporary and will not last for long. **General reactions** including headache, fatigue, muscle aches/pain, joint pain, nausea, vomiting, rash, dizziness, feeling feverish and chills may also be experienced by some participants. These effects can last for a couple of days.

Severe allergic reactions (anaphylaxis) to a vaccine are rare but can occur with any vaccine and can be fatal. In the unlikely event of this occurring, medications for treating allergic reactions are kept in the clinic room and the clinical study team are appropriately trained in the management of anaphylaxis.

Challenge related

The natural carriage of Spn in the nose is quite common in the general population across different age groups and most of the time it does not cause any symptoms. Mild forms of infection from Spn, such as otitis (ear infection) and sinusitis, are many times more common than serious infections (pneumonia, bloodstream, meningitis). The incidence of serious infection is 20/100,000 people. The study is designed to ensure that any risk is minimal. After inoculation, you may experience headache, cough, sore throat, nasal obstructions/discharge, fever/chills, malaise, rash and earache. We will monitor any symptoms following the inoculation as well as the samples we collect from you. We will give you instructions and provide you written guidance on what to expect and actions that might be required from you. We will also supply you with the antibiotic amoxicillin, which is effective against the challenge bacteria, and we will give you instructions about how to use in case it is indicated.

Other potential risks from taking part in this research study

Blood sampling may cause slight pain and sometimes bruising. Occasionally, people feel light-headed, nauseous, or faint. The amount of blood taken at each visit is small and should be well tolerated by healthy adults.

What if we find something unexpected?

As we carry out several medical tests throughout the study, it is possible that we pick up previously unknown health issues (e.g. high blood pressure, abnormal blood results). If abnormal results or previously undiagnosed conditions are found during the study, these would be discussed with you and, if you agreed, your GP would also be informed of these results. Sometimes incidental medical findings might require your GP to carry out further investigations such as blood tests, scans or referral to specialists.

During the screening process, we will test your blood for HIV, hepatitis B and hepatitis C. In the UK, healthcare professionals are legally obliged to report any new suspected cases of hepatitis B and hepatitis C to the UK Health Security Agency (UKHSA). If you are found to have hepatitis B or C, we will be required to send a report to the UKHSA, including your personal contact information. It's important to note that you cannot opt out of this due to UK reporting requirements.

Will I be taking any antibiotic?

In this study we may use an antibiotic called amoxicillin. It comes as tablets, and it is taken 3 times per day for 5 days. If you are required to take amoxicillin, the study team will advise you on how to take it and further information is also found on the safety information leaflet. We use this antibiotic because it is effective against our challenge bacteria and we have not needed to use a different antibiotic in any previous studies with this bacteria. However, in the very rare case that this antibiotic does not work, we will advise you on the most appropriate course of action, which

might include switching you to an alternative antibiotic. Most people do not have any side effects from amoxicillin, but general side effects of antibiotics can occur. These might include upset stomach, nausea, diarrhoea and rash.

Are the any benefits from taking part?

There is no direct benefit to you of taking part in this study. You will be contributing to generating knowledge on pneumococcal vaccines which will potentially aid the development of improved vaccines. Participants will benefit from receiving PCV15 vaccine which protects against 15 pneumococcus serotypes. At the point of unblinding, PCV15 will be offered for participants in the placebo arm that wish to take the vaccine. No specific additional medical care will be provided through participation, and medical procedures are performed with the aim of determining eligibility and safety during the trial.

What other considerations do I need to know?

- **Contraception:** We require participants who could become pregnant to use contraception for at least one month before they receive their first vaccination, and for the entire duration of the study. Unless you are post-menopausal or have had a permanent sterilisation procedure, you will be required to use one of the contraception methods listed below and to have a pregnancy test at screening and before vaccination and challenge.

Acceptable effective contraception methods include:

- Oral, injected or implanted hormonal contraceptives (“the pill”, “the depot”)
- Intrauterine device (IUD) or intrauterine system (IUS) (“the coil”)
- Condoms or occlusive cap with spermicide
- Sole sexual partner has had a vasectomy
- Complete abstinence from sexual intercourse which could result in pregnancy (please note this must be in line with participants’ normal lifestyles, and declarations of abstinence during the study will not be sufficient)

- **Pregnancy:** If you were to become pregnant during the study, you should tell us immediately so that we can review certain study procedures and determine the appropriate safety follow up. With your consent we would follow you up to birth or end of pregnancy. Study procedures such as vaccination and inoculation will be suspended if pregnancy detected before them. If pregnancy detected after inoculation, we will need to assess the need for antibiotic treatment and discuss it with you.
- **Other vaccinations:** If during the study you require any vaccinations for health, travel, or occupational reasons, you should inform the study team before you have the vaccine. We ask you not to have any vaccines within 28 days (before or after) of the study vaccine. Exceptions to this are flu vaccines and COVID-19 vaccines which can be given within 14 days (before or after) of the study vaccine.
- **Identification:** We will ask you to bring a form of photographic Government issued ID to your first visit and provide your National Insurance number. A copy will be kept securely and checked at each visit by authorised members of the study team.
- **Medications:** If you begin taking any new medications during the study (prescribed or over the counter), please inform the study team.
- **Blood donation:** Under current UK regulations, participants must not donate blood during their involvement in the study. You will be able to restart blood donation once your last study visit has been completed.
- **Taking part in other clinical studies:** You should not take part in other clinical studies where drugs or vaccines are administered or where repeated blood samples are taken.

Do I have to take part?

No, it is completely up to you. Your decision will not result in any penalty or changes to your standard medical care. If you do decide to take part, you will be given this information sheet to keep (or be sent it electronically) and will be asked to sign a consent form.

You may also change your mind about participating at any time and withdraw from the study. This would not result in any penalty or change to your medical care. We would use the samples and

data we have collected from you in our analysis of the study up until the point you informed us that you wanted to withdraw, unless you specifically request that the samples be destroyed before being analysed.

In exceptional circumstances (for example, if you were to become very unwell during the study), your participation in the study may be stopped early by the study team or the sponsor of the trial. If this occurs, we may ask you to still attend safety follow-up visits with your consent.

Will I be reimbursed from taking part?

Study participants would be reimbursed for their time, travel, and the inconvenience of taking part in the study. The maximum reimbursement for any volunteer who completes all visits of the **main study** is up to £920. All participants will be reimbursed based on the following figures:

Study Visit	Visit type	Reimbursement
V0	Screening	£110
V1	Vaccination	£110
V2	Vaccination Follow-up	£90
V3	Re-screening	£110
V4	Inoculation with Spn3	£110
V5	Inoculation Follow-up Day 2	£90
V6	Inoculation Follow-up Day 7	£90
V7	Inoculation Follow-up Day 14	£90
V8	Inoculation Follow-up Day 28	£90
N/A	Full completion of post-inoculation diary	£30

You may also receive reimbursement for any unscheduled visits you are asked to attend by the study team. You would be reimbursed £90 per unscheduled visit. We will also offer a £10

payment (a shopping voucher of equivalent value) to study participants (once enrolled) that refer a friend that takes part in the study.

The sum reimbursed is on a pro-rata basis, so, if for example, you choose to withdraw halfway through the study, or do not complete all study procedures, we would calculate your reimbursement based on the visits you have attended and samples that have been obtained. The reimbursement provided is considered to be reasonable amounts to cover the costs of participating in this research. There should not be any consequences for tax or benefits purposes. The reimbursement will be provided at different intervals of study involvement.

Payments are made directly by bank transfer from the research site Oxford Vaccine Group to you. For this reason, we require participants to provide their bank details at the screening visit. Bank details are kept confidential. Personal information such as your name, bank details and national insurance number may be shared with the University finance team to process or verify your reimbursement payments. Financial auditors may also audit the records where this information is held. All confidential data will be stored according to the UK General Data Protection Regulation.

What will happen to the samples I give?

- The study samples will be analysed in University of Oxford and NHS laboratories.
- Samples taken will be used to look at your immune responses to the vaccine and to pneumococcus. Some bloods and nasal cells would be used to look at the pattern of genes being actively used by your body in response to the vaccine and during pneumococcal carriage. The response to infection and to vaccines is in part genetically controlled, so knowing the pattern of genes that are being used may help us to understand how individuals respond to vaccination and to pneumococcal carriage.
- Clinical safety blood samples are sent to local NHS laboratories and follow local sample labelling requirements (which may include personal identifiers). As part of processing clinical safety blood samples, local NHS laboratories may be required to add the results to your medical records.

- We will send samples to other researchers working with us on this research project, including researchers within and outside the UK and the study funder (MSD, a commercial company) to conduct some sample analysis.
- Samples sent to research laboratories for processing will not have personal identifiers (they will be identified by study number and participant number only). However, your DNA is unique to you so it can never be completely anonymous.
- If you choose to take part in this study, you will be asked for permission to store samples (including cells and DNA) in the Oxford Vaccine Centre Biobank. This is a collection of samples, like a library, and allows the samples to be stored once this study is finished. You can choose to say no to the biobank but continue with this study. If you decide not to consent for the biobank, the remaining samples will be destroyed.

What happens to my data?

An online screening questionnaire is used to determine your eligibility. For those participants who proceed to take part in the study, the data from the screening questionnaire will be kept with their study records. For those who do not proceed to participate in the study, all answers from the screening questionnaire will be kept until the end of the study recruitment period and then will be deleted. If you supplied your medical history or underwent screening but were not vaccinated in the study either because you were not eligible or decided not to take part, then any data collected will be kept until the end of the study.

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

You will be given a study number, which will be used on study paperwork and samples. We will be using information from your medical records in order to undertake this study and will use the minimum personally identifiable information possible. We may need to view your ID (driver's licence, passport or national ID card), and will record either your national insurance or passport

number for TOPS database registration and payment processing. This will be taken at the screening visit. We will securely retain this information until the end of the study. Your bank details will be stored for 7 years or in line with Oxford Vaccine Group financial policy.

General Data Protection Regulation (GDPR) requires 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, based in the United Kingdom, is the Sponsor for this study and the 'data controller' and will use your personal information to contact you about the research study and 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. Your personal information will be kept confidential and handled in accordance with data protection laws in the UK. We will be using information from you and your medical records to undertake this study. We will use the minimum amount of personally identifiable information. Research data may be transferred to, and stored at, a destination outside the UK and the European Economic Area. Identifiable data will be removed and any data transfer will be done securely and with a similar level of data protection as required under UK law.

Study staff will ensure that participants' data is pseudo-anonymised other than for uses (e.g., notification to UKHSA and communication with the GP) about which the participants will be consented for. Participants will be identified by initials and a participant ID number on the study paperwork. Your email address is required for the electronic diaries, in order for them to function. Only designated site staff and the data managers(s) will have access to view your email address and you will need to consent to this.

We may disclose your personal data to our third-party service providers to carry out activities specifically for the purpose of this research study and as explained in this information sheet, for example text messaging service providers/companies to send study-related text messages to you. Any third-party service providers are required to take appropriate security measures to protect your personal data in line with University of Oxford policies. We do not allow our third-

party service providers to use your personal data for their own purposes, but rather to only process your personal data for specified purposes and in accordance with our instructions.

Study data may be stored electronically on a secure server by the University IT team, and paper notes will be kept in a secure location at each study site or as outlined in local SOP's. We will store the research data and any research documents with personal information, such as consent forms, securely for up to 25 years after the end of the study, or as per national regulatory requirements. Anonymised research data may be kept indefinitely. It will not be possible to identify you in any publication or report.

You can stop being part of this study at any time, without giving a reason, but we will keep the information about you that we have already obtained, including samples and symptom diary data. If you prefer, you can request for the samples to be destroyed (if they have not already been analysed).

If you have agreed that samples can be retained for future research, then your personally identifiable information will be kept with restricted access solely for the purposes of sample management. Samples will be provided for future research only in a form that does not identify you.

At the completion of the study, unless you consent otherwise (e.g., if you request to be informed of other studies), your personal details will not be used to contact you other than in exceptional circumstances concerning your safety. If you consent to take part in another study carried out by Oxford Vaccine Group personal information and medical information including blood test results may be accessed to avoid unnecessary repetition.

If you agree to future contact (e.g., to be informed of other studies) we will continue to store your consent form within the study records and personal information (e.g., name, DOB and contact details) in a password protected database. This will be archived on a university server with restricted access and kept indefinitely, or until the study team feel that it would no longer be

required, at which point it will be deleted. This will be held separately from the study data, and you can request at any time to have your details removed. If you have not consented to being approached for future studies, your contact details will be stored for 5 years after the end of the study to provide copies of study results and allow sufficient time for study data cleaning.

General Data Protection Regulation (GDPR) 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

You can find out more about how we use your information:

- At https://www.hra.nhs.uk/planning-and-improving-research and www.hra.nhs.uk/patientdataandresearch
- By asking one of the research team
- By sending us an email to info@ovg.ox.ac.uk
- By ringing us on 01865 611400

Additional Information

- The study is **sponsored** and organised by the University of Oxford.
- The study is **funded** by Merck Sharp & Dohme.
- **Private insurance:** If you have private medical or travel insurance participation in a study will not usually affect your cover if conditions are unrelated to the study, but to be certain you must tell your provider before you take part.
- **Confidentiality:** Information collected during the study will be treated confidentially. We will inform your GP that you are enrolled in the study and provide information so that your medical records can be updated. You will be required to consent to allow us to access your medical records, via your GP or via electronic records, to check your health before enrolling in the study and during the study, if you have medical events.

Responsible members of the University of Oxford, the relevant NHS Trusts involved in the research and the regulatory agency responsible for clinical studies in the UK, the MHRA, may also be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations. No-one else will be told that you are involved in the study.

- **TOPS database:** Volunteers participating in this study must not be enrolled in another study that involves investigational medicines or vaccines at the same time. The Over-Volunteering Prevention System (TOPS) is a national database which helps prevent volunteers from taking part in too many clinical studies. To check this, we will need your passport number (for all non-UK citizens) or National Insurance number (UK citizens). We will update the database when you receive a vaccine. The data is retained in TOPS for 2 years if you do not receive a dose of vaccine.
- **New Information:** Sometimes during a study new information becomes available that is important to let you know about. This may mean signing a new consent form. We will review new information or safety concerns and you would be kept fully updated.
- **Harm:** The investigators recognise the important contribution that volunteers make to medical research and make every effort to ensure your safety and well-being. The University of Oxford, as the 'research sponsor', has arrangements in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. In the event of harm being suffered, while the sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor may advise you of further action and refer you to a doctor within the NHS for treatment, if necessary. If you are referred to the NHS during the study, then NHS indemnity operates in respect of the clinical treatment which may be provided.

We will provide compensation for any injury caused by taking part in this study. We will pay compensation where the injury probably resulted from:

- A drug being tested or administered as part of the study protocol.
- Any test or procedure you received as part of the study.

Any payment would be without legal commitment (please ask if you wish for more information on this). We would not be bound by these guidelines to pay compensation where the injury

resulted from a drug or procedure outside the study protocol or where the protocol wasn't followed.

- **Complaints statement:** If you wish to report a concern about any aspect of the study, you can contact your local study team at 01865 611400 and info@ovg.ox.ac.uk. You may also contact the sponsor, the University of Oxford, RGEA (Research Governance and Ethics Assurance) office on 01864 616480, or email at rgea.complaints@admin.ox.ac.uk. Reporting a concern will not affect the medical care you receive now or in the future.
- **Results of this research:** The results will be published in a scientific medical journal and may be presented at scientific conferences or meetings. You will be provided with a summary of the results and access to the full publication. This can take up to 2 years after the study is completed. **Your individual results would not be identifiable, and you would not be identified in any report or publication (de-identified).** The research data will be shared with collaborators who are organising or funding the research. Data from this study may be used to file patents or licence vaccines in the future or make profits in other ways. You would 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.
- **Review:** This research has been looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by South Central - Oxford C Research Ethics Committee. The Oxford Vaccine Centre Patient Public Involvement group have reviewed the main participant-facing documents associated with this study (Participant Information Sheet, Consent form, and advertising materials).

The Medicines and Healthcare products Regulatory Agency (MHRA), which regulates the use of all medicines in the UK, has reviewed the study design and has granted permission to use this unlicensed vaccine in this clinical study.

Register for the study or discuss with the team

We hope this information sheet has given you enough information to decide whether to volunteer for this study. If you would like further information about participating in research, please visit the following website: http://www.nhs.uk/conditions/Clinicaltrials/Pages/Introduction.aspx.

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Telephone: 01865 611400 info@ovg.ox.ac.uk
www.ovg.ox.ac.uk

For independent advice about participating in this study, you may wish to contact your GP.

If you are interested in taking part in this study, then please complete the online screening questionnaire at:

https://www.ovg.ox.ac.uk/studies/rationale15

If you have further questions about the study, please contact us at:

Email: info@ovg.ox.ac.uk **Tel:** 01865 611400