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UNIVERSITY OF OXFORD

JENNER VACCINE TRIALS
NUFFIELD DEPARTMENT OF MEDICINE

CCVTM, Churchill Hospital, Old Road,
Headington, Oxford, OX3 7LE

PARTICIPANT INFORMATION SHEET: HIV-CORE 0051

A study to assess new candidate HIV vaccines in HIV-1/2-negative adults

"A phase 1/2a open label trial to assess safety and immunogenicity of candidate T-cell vaccines ChAdOx1.HTI and MVA.HTI given sequentially to HIV-1/2-negative volunteers in Oxford, UK"

You are invited to take part in a study to test a new vaccine against HIV. Before you decide to take part, it is important that we explain why this research is being done and what it will involve.

You should be aged 18-65 years, HIV-negative and healthy. Women who are interested in participating should not be pregnant, breast-feeding or intending to become pregnant during the study period.

Participating in this trial does not mean that you will be protected against HIV. It is important that you continue to protect yourself against HIV infection.

During the trial you will be counselled on reducing your risk of infection and receive information on available methods to reduce your risk.

Please take time to read the following information carefully and discuss it with friends, relatives or your GP if you wish. Please ask us if there is anything that is not clear or if you would like more information.

What is the purpose of this trial?

An estimated 36.7 million people are chronically infected with Human Immunodeficiency Virus (HIV), the virus that causes AIDS. Vaccination is the most effective way to prevent many infectious diseases, but developing effective vaccines against HIV is extremely challenging. One of the main reasons for this is the extraordinary ability of the virus to change itself so that the human immune system does not recognise it and the virus escapes protective responses.

Pre-clinical studies on the vaccines we test in this trial have been performed in small animals and non–human primates, without safety concerns.

These vaccines are currently being administered to a small number of people living with HIV (approximately 30 at the time this document is written) in clinical trials with the aim of studying if they are safe and if they can help control the infection in those who are affected.

The aim of this trial you are invited to take part is to find if the vaccines are safe and if they induce an immune response against HIV in people without HIV infection.

This is the first time that these particular vaccines will be given sequentially to healthy, HIV negative individuals.

What is the vaccine being tested?

Each participant will receive two vaccines eight weeks apart; the purpose of the second vaccine is to increase the effect of the first vaccine.

The vaccines are called ChAdOx1.HTI and MVA.HTI and they both consist of two parts:

1) The first part is known as a carrier (also called a 'vector'). Vectors used in this trial include a chimpanzee adenovirus called ChAdOx1, which is similar to human common cold viruses, and a type of smallpox virus called modified vaccinia virus Ankara (MVA). These vectors cannot multiply in the human body and are harmless viruses. These vectors have been safely used in research vaccine studies against many different infectious diseases in Oxford and more widely.

2) The second part of each vaccine contains small segments of HIV called HTI. These segments are completely synthetic and do not contain live HIV, therefore they cannot give people HIV infection or AIDS. They are present only for the purpose of inducing immune response against them.

It is absolutely impossible to get HIV infection or AIDS form these vaccines.

Do I have to take part?

No. It is up to you to decide whether or not to take part. 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 are free to withdraw at any time and without giving a reason, but you may be asked to return to the clinic for follow up for safety reasons.

Can I take part?

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

- Be a healthy, HIV-negative adult aged between 18 and 65 years
- Be able and willing (in the Investigator's opinion) to comply with all study requirements
- Allow the Investigators to discuss your medical history with your GP
- Practice continuous effective contraception for the duration of the study (women of child-bearing potential only)
- Refrain from blood donation during the course of the study

You cannot participate in this study if:

- You have participated in another research study in the last 30 days
- You are planning to participate in another study at the same time as this study
- You have previously received an investigational vaccine likely to impact on interpretation of the trial data (e.g. Adenovirus vectored vaccine)
- You have had immunoglobulins and/or any blood products (such as a blood transfusion) in the 3 months preceding your involvement in this trial
- You have received a live attenuated vaccine in the 60 days preceding your involvement in this trial or plan to receive it within 60 days after study vaccination
- You have received another vaccine including influenza vaccine in the 14 days preceding your involvement in this trial or plan to receive it within 14 days after study vaccination
- You have a history of angioedema
- You have any bleeding disorders
- You have problems with your immune system
- You are pregnant, breast feeding or intend to become pregnant during the study
- You have a history of a severe allergic reaction to a vaccination
- You have a history of cancer
- You have a history of a serious psychiatric condition that may affect participation in the study
- You have any other serious long-term illnesses requiring hospital follow-up
- You drink on average more than 42 units of alcohol a week (a pint of beer is 2 - 3 units, a small glass of wine (125mL) one unit and a shot of spirits (25mL) one unit)
- You have injected drugs at any time in the last 5 years
- You have HIV, hepatitis B, hepatitis C or untreated syphilis infection
- You report high-risk behaviour for HIV-1 infection

Mild conditions which are well-controlled, would not automatically exclude you from participating. 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.

You must be able to comply with all of the trial requirements and be able to attend all of the follow up visits.

How often do I need to attend?

You will be asked to attend for 13 study visits over a period of 8 months.

What do I have to do if I agree to take part?

Screening Visit

If you decide you would like to take part in this trial, you will need to attend a screening visit up to 1 month before the vaccination day that should last for about two hours. The screening

visit, the vaccination and all of the post-vaccination follow-up visits will take place at the Centre for Clinical Vaccinology and Tropical Medicine (CCVTM), at the Churchill Hospital in Oxford.

On the first visit (screening visit) the study doctor or nurse will discuss the study in detail with you to make sure that you fully understand what the study is about and what is involved if you decide to take part, and that you are happy to give written consent to take part in the study.

If you decide to take part we will give you a copy of the consent form that you have signed which you can keep for your records together with this information sheet. We will give you an appointment schedule for the study visits. If appropriate, we will ask you to ensure that you use effective contraception throughout the study (women of child-bearing potential only).

We will ask you questions about your health and any medications you are taking and give you a physical examination. Your pulse rate, blood pressure and temperature will be recorded. We will also ask questions to ensure that you are not at risk of HIV infection. A blood sample will be taken in order to confirm that you are eligible to take part. This will include tests for HIV, Hepatitis C virus, Hepatitis B virus and syphilis infections. These tests will be explained to you in detail.

If we identify any reason that would prevent you from taking part in this study this will be discussed with you. If a minor abnormality is noted on a screening blood test, a repeat test might be required to verify it.

With your permission, we will inform your GP of your participation in the study and request a copy of your medical summary from your GP to confirm you do not have any reasons to be excluded from the study. You will be asked to sign a letter addressed to your GP in order to consent them to release relevant medical information about you. If your consent to contact your GP and haveaccess to your medical history is not given, you will not be able to take part in the study. You will be notified within two weeks to inform you if you are eligible to take part.

We will ask you to refrain from participating in other clinical trials at the same time. In addition we will register you on the TOPS database (www.tops.org.uk), which is a confidential national database of healthy volunteers that identifies volunteers participating in studies, to minimise the risks that can come from over-volunteering. We will enter into the database only:

- your National Insurance number (if you are a UK citizen)
- your passport number and country of origin (if you are not a UK citizen)
- the date of your last dose of study vaccine

Considerations before taking part in this study

Blood Donation: Under current UK regulations, participants will not be able to donate blood during the course of the study.

Private Insurance: If you have private medical or travel insurance you are advised to contact your insurance company before participating in this trial, as involvement may affect the cover provided.

Contraception: It is currently unknown the vaccines being tested are safe during pregnancy. For this reason, it is important that all women of child-bearing potential use adequate contraception throughout the trial period. Acceptable forms of contraception include; well established use of oral, implanted or injected hormonal contraceptive methods; having an IUD or IUS fitted; if you have had a total abdominal hysterectomy; using a barrier method such as a condom or cap; if you have a single male partner who is sterilised; or if total abstinence is your usual practice. This will be discussed with you at the screening visit. If you were to become pregnant during the trial you must tell us immediately and you will not receive any further vaccinations, although we will ask to follow you up for safety reasons. Male participants with female partners are required to use barrier methods for the purposes of contraception until 4 months after the last vaccination.

Vaccination Visits

On the vaccination visits you will be given an injection into the muscle over the shoulder region of your non-dominant arm. We will monitor you for 30 minutes at the clinic to ensure that there is no serious reaction to the vaccine.

Before going home, you will be given the log in for a web based electronic diary and telephone number(s) to call the doctor or nurse in case you have any side effects or any concerns about the vaccine.

During the next six days you will be asked to keep a daily record of your temperature and any 'flu'-like symptoms that you might experience, using the web based electronic diary.

During the vaccination visit, blood samples will be collected. On three instances (at the vaccination visit, 1 and 4 weeks after the second vaccination), we ask you to collect your faeces. For this, you will be given a pot (at the screening visit) in order to collect faeces at home (you can collect faeces up to 24h before coming to the visit and store in the fridge in the provided storage system).

To ensure the safety of the participants, the first participant receiving ChAdOx1.HTI will be vaccinated alone. A safety review will be carried out 48 hours after the vaccination, and if there are no safety concerns, another two participants will be vaccinated. Another safety review will be carried out 48 hours after the second and third participants are vaccinated, before proceeding with the vaccination of the last 7 volunteers. The same procedure will be followed for the first three participants receiving MVA.HTI.

Subsequent Visits

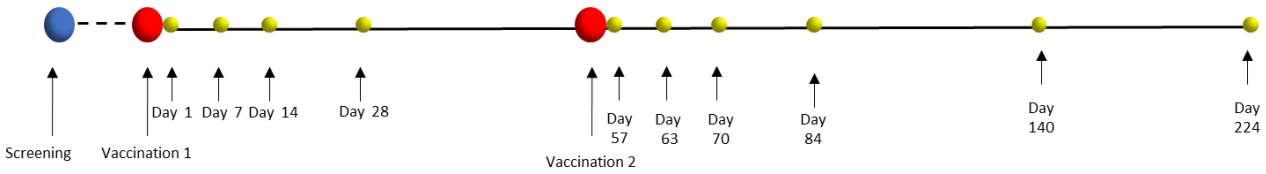
On every subsequent visit we will ask questions about your health and, if necessary, we will carry out a physical examination. Blood will be taken at each visit. The amount of blood taken

at each visit will vary as different amounts are required to assess your response to the vaccine over time. You will have between 10 and 100 ml (roughly 1½ – 6 tablespoons) of blood taken at each visit (on average, just under 4 tablespoons per visit) with a total of approximately 500 ml taken over a period of 8 months, about the same as the amount that would be taken from regular blood donors at one visit to a Blood Donation Centre.

There might be a case in which your blood needs to be retested or a urine sample taken to confirm test results. In this case, the study staff would take a sample of your blood and collect urine samples, as needed. This may happen during a scheduled visit or you may be asked to come back to the clinic for an additional visit.

The chart below gives a summary of the visits involved in the study:

For this trial we plan to recruit a maximum of 10 people. Each volunteer will receive one dose each of the two vaccines.



Number of visits	13
Duration of study	8 months (224 days)
Vaccination visits	Day 0 and 56
Blood samples	Screening visit, days 0, 1, 7, 14, 28, 56, 57, 63, 70, 84, 140 and 224
Faeces sample	Day 0, 63 and 84

What are the risks of taking part?

The vaccines used in this trial have been tested on mice (ChAdOx1.HTI and MVA.HTI) and non-human primates (MVA.HTI) and they are currently being tested on a small number of people living with HIV (approximately 30 at the time this document was written), without safety concerns.

Similar vaccines using the same vectors have been given to hundreds of volunteers with no significant or serious side effects in Oxford and more widely.

However, this is the first time that these particular vaccines will be administered sequentially to healthy HIV negative individuals, and given the small number of humans they have been administered to, there might be risks associated with their use we are not aware of.

Risks of vaccination

Side effects of Vaccination

Although the vaccine has only been tested on a small number of humans, other ChAdOx1 and MVA viral vector vaccines have previously been administered in many other clinical trials. We can predict from past experience what the symptoms should be like with this new vaccine. We expect that symptoms will be mild in strength most of the time, although symptoms may also be moderate or severe. All symptoms should resolve completely within a few days.

Local reactions

After the first vaccine with the adenoviral vector (ChAdOx1.HTI), we expect local reactions to occur in most people. Local pain, redness, warmth, and swelling are the most likely local reactions. In general these side effects are expected to be mild. After the second vaccine with the MVA vector we expect the same local symptoms to occur in approximately 60% of the participants, but these may be more intense in nature. However, these symptoms should resolve within a few days.

General Reactions

After the first vaccine with the adenoviral vector, we expect general adverse events to be observed in the majority of people. Fatigue, headache, and malaise are the most common general reactions. Other symptoms include fever, chills, joint and muscular pain. The majority of these adverse events are expected to be mild to moderate in severity and to have resolved by 72 hours post vaccination.

After the second vaccine with the MVA vector we expect the same systemic symptoms to be more intense. In addition, after the MVA vectored vaccine, gastrointestinal symptoms as nausea and abdominal cramps have been reported by approximately one third of the recipients. However, these symptoms should resolve within a few days.

Severe Reactions

The risk of severe adverse outcomes in this trial is very low. However, unexpected outcomes are possible.

With any vaccination, there is a risk of rare serious adverse events, which may be related to the nervous system, or the immune system, like an allergic reaction.

An allergic reaction can be recognized by itchy skin rash, swelling of the face, difficulties in

breathing and swallowing or by a sudden drop in blood pressure. If such reactions occur, they usually start very soon after vaccination. That is why it is important that you stay at the study site for at least 30 minutes after vaccination, where all medical equipment and personnel are available to treat an allergic reaction.

Reactions in the nervous system are also extremely rare following vaccination and can cause an illness called Guillain-Barré syndrome. Guillain-Barré syndrome is an illness in which people can develop severe weakness and can also be fatal. These adverse events have not happened with other similar adenovirus or MVA based vaccines. If you experience unexpected events, or become in any way concerned you should contact the Investigator using the contact details provided in this information sheet.

Risks of taking blood samples (venepuncture)

Having blood taken may cause discomfort, bleeding or bruising where the needle enters the body and, in rare cases, light-headedness and fainting.

We do not foresee that the amount of blood taken during the study will cause harm to your health. It would not be expected for this amount of blood taken to cause anaemia. However, we will check for anaemia at regular intervals during the study.

Incidental findings

We would notify your GP that you were taking part in this study. If abnormal results or undiagnosed conditions are found in the course of the study these would be discussed with you and, if you agreed, your GP would be informed of these results to arrange further follow-up (we would not report them to your GP or anyone else without your permission).

If at screening, or any time during the study, a blood sample indicates that you may be positive for HIV infection, we will take a second sample to confirm this result. In the event that this is a true positive result we will withdraw you from the trial and discuss the implications with you before referring you for treatment and/or support.

False positive results on HIV tests

As a result of vaccination, there is a theoretical risk you may test positive for antibodies against HIV and these antibodies may persist in the future. In the unlikely event that this happens, it is a result of the vaccination and NOT because of HIV infection. There is a simple blood test which can tell if you have contracted HIV: this test, called polymerase chain reaction (PCR), is able to detect even small amounts of virus in the blood. Before and after the trial we will do PCR to verify that you are not infected with the HIV virus. It is absolutely impossible to contract an HIV infection or AIDS from these vaccines.The presence of antibodies that you might have developed as a result of the vaccination will not alter the result of the PCR test. However, according to the current regulations of National Blood Service, HIV antibody positive tests results will exclude you from being a blood or tissue donor as long as you remain positive, and may impact upon the ability to be an organ donor.

If you do develop antibodies to the HIV virus we will, with your permission, write to your GP explaining this and give a copy of the letter to you to keep for the future. In brief, the letter will state that you have generated antibodies against HIV proteins, as a result of the vaccination. However, this test result should not be taken as a marker of current or previous infection with HIV and has no impact on your health status. You will present no risk of transmission of HIV; this status can be confirmed if necessary by analysis of plasma for HIV viral RNA by PCR. The same result will impact upon the ability to be a blood, tissue and possibly organ donor. Should you be required to share this information with a third party, such as an insurance company, we will be happy to provide verbal or written clarification as needed.

Administration of the study vaccines won't affect your ability to be a blood, tissue or organ donor if antibodies against HIV are not detected in your blood by the standard HIV screening tests.

Social harms

The research team will keep your participation in this trial confidential. However, it is possible that others may perceive you to be at risk of HIV infection or stigmatise you should you decide to let them know about your involvement in the trial. If you have any concerns or difficulties, trial staff will provide assistance and support.

Will the study benefit me?

You will receive no direct benefit from this study. The aim of the study is to see whether the vaccines are safe, but it is not intended to grant you protection against HIV. **It is important that you continue to protect yourself against HIV infection.** Knowledge gained from this study may in the future help others to avoid HIV infection.

Can I take part in this study if I am pregnant?

If you are pregnant or are planning on becoming pregnant in the near future, or if you are breast-feeding, you should not take part in this study. The safety of the vaccines in pregnancy is not known. You will be asked to use an effective method of contraception during the study, if this is appropriate and if you are not already doing so. Guidance will be provided to participants on what constitutes an effective method of contraception in the context of this trial. Contraception will need to be continued for the duration of the study. If you become pregnant during the study, you should tell us immediately. Should this happen you will not receive any further vaccinations but would remain under follow up until after delivery.

Will I be able to participate in other trials in the future if I have received this vaccine?

This depends on the specific criteria of each trial and it would need to be discussed on an individual basis.

What if new information becomes available?

Sometimes during the course of a trial, new relevant information relevant to the trial becomes available. If this happens, we will tell you about it and discuss whether you want to, or should,

continue in the study. If you decide to continue to take part, you will be asked to sign an updated consent form. On receiving new information, we may 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 for other reasons.

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

If, at any time after agreeing to participate, you change your mind about being involved with this study you are free to withdraw without giving a reason. If you withdraw we would not usually perform any more research procedures, although occasionally we might need to offer you a follow up visit for safety purposes, for example to check the injection site or a blood result. Your decision will not result in any penalty. Unless you state otherwise, any blood taken whilst you have been in the study will continue to be stored and used for research as detailed above. You are free to request that your blood samples are destroyed at any time during or after the study. If you choose to withdraw from the trial, your standard medical care will not be affected.

What if something goes wrong?

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 trial.

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 can advise you of further action and refer you to a doctor within the NHS for treatment, if necessary. NHS indemnity operates in respect of the clinical treatment which may be provided if you needed to be admitted to hospital.

Will I be paid for taking part in this study?

You would be reimbursed for your time, travel and the inconvenience of taking part in the study. The reimbursement for completion of the whole study is £515.00. You would be reimbursed £25 for the screening visit. For subsequent visits you will be reimbursed for your time, travel and the inconvenience based on the following figures:

- Travel expenses: £15 per visit
- Inconvenience of blood tests: £10 per blood donation
- Time required for visit: £40 per vaccination visit and £20 per follow up visit

The sum reimbursed is on a pro rata basis, so, if for example, you choose to withdraw half way through the study we would calculate your reimbursement based on the visits you have attended and samples that have been obtained. You may also receive reimbursement for any

unscheduled visits you attend (if blood tests have to be repeated). You would be reimbursed £40 per unscheduled visit.

Complaints statement

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Dr Paola Cicconi on 01865 611413 or via email: vaccinetrials@ndm.ox.ac.uk. Alternatively, you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email ctrg@admin.ox.ac.uk.

Would my taking part in this trial 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. The information is available to the trial team, authorised collaborators, ethical review committees, government regulatory agencies and the Sponsor (University of Oxford), who can ask to assess the trial data. Monitors from the University of Oxford may be given access to data for monitoring and/or audit of the trial to ensure we are complying with regulations. They are bound by the same confidentiality rules. Any information about you that leaves the hospital/clinic will have your name and address removed so that you cannot be recognised from it.

Trial results will be published in a scientific journal but nothing that could identify you will be included in any report or publication.

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, so we may inform you of opportunities to participate in future vaccine related research. This is entirely optional and your participation in this study will not be affected by your decision to allow or not allow storage of your contact details beyond your participation in this trial.

Your details will be stored electronically on a secure server and 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 and you can ask us to have your contact details removed from our database at any time.

What will happen to any samples I give?

The blood tests will include a full blood count, blood chemistry and liver function tests at selected visits, to ensure that the vaccines are safe. In addition, a blood sample will be taken at each visit for research laboratory tests that will measure your immune response to the vaccine. Blood samples will be labelled with your unique study code only, before sending to the appropriate laboratory for analysis.

The safety blood samples collected during this study would be stored and analysed in the Oxford University Hospital NHS Foundation Trust and University of Oxford research laboratories in the first instance. However, as part of this project, research samples may be sent to our collaborating partners both within and outside the UK. These samples would be stored with your unique study code only.

If you choose to withdraw from the study, all the samples collected prior to withdrawal will be analysed. No further samples or information will be requested from you after the date of withdrawal, unless required for safety reasons.

At the end of the study with your consent, blood and faecal samples may be stored long-term for future research use in the Oxford Vaccine Centre Biobank as described in a separate information sheet. You will be asked to sign a separate consent form for this. If you choose not to allow the future use of your remaining samples, you may still participate in this study and your samples will be destroyed at the end of the trial, in accordance with local SOPs and the Human Tissue Act 2004.

What will happen to my data?

We will be using information from you and your medical records in order to undertake this study. Research is a task that we perform 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 the minimum personally-identifiable information possible. We will keep identifiable information about you such as contact details for a minimum of 6-12 months after the study has finished. The need to store this information for longer in relation to licensing of the vaccines will be subject to ongoing review. For effective vaccines that may be licensed, we may store research data securely at the University of Oxford for at least 20 years after the end of the study, subject to adjustments in clinical trials regulations. In addition to the de-identified 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, 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. At the completion of the study, unless you consent otherwise (e.g. if you request to be informed of other trials), your personal details will not be used to contact you other than exceptional circumstances concerning your safety. If you consent to take part in another study carried out by the Jenner Institute, personal information and medical information including blood test results may be accessed to avoid unnecessary repetition.

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

Your rights to access, change, or move your personal information may be limited, as we need to manage your information in specific ways 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

What will happen to the results of the research study?

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. 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 de-identified data from this study will be shared with the collaborating 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.

Who is sponsoring, organising and funding the research?

The study is organised and sponsored by the University of Oxford. The study is funded through financial support from the European Commission within the Horizon 2020 research programme.

Who has reviewed the study?

This study has been reviewed by the National Research Ethics Service (NRES) – XXXXXXX and has been given a favourable ethical opinion. 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.

Further information and contact details

We hope this information sheet has answered all of your questions. If you would like further information about participating in research please visit the following website: http://www.nhs.uk/conditions/Clinical-trials/Pages/Introduction.aspx.For independent advice about participating in this trial you may wish to contact your GP. If you would like to speak to one of our team members to discuss any aspect of this trial or **if you are interested in taking part in the study, please contact us**:

Recruitment Coordinator
Centre for Clinical Vaccinology & Tropical Medicine
Churchill Hospital, Old Road, Headington, Oxford, OX3 7LE
Telephone: **01865 611406**
Email: **vaccinetrials@ndm.ox.ac.uk**