Oxford Vaccine Group
University of Oxford
Centre for Clinical Vaccinology and Tropical Medicine,
Churchill Hospital, Headington, Oxford OX3 7LE
Telephone: 01865 611400 info@ovg.ox.ac.uk
www.ovg.ox.ac.uk

PARTICIPANT INFORMATION SHEET

Full Title: A phase 1, first-in-human, safety and immunogenicity study of a Lassa fever vaccine, ChAdOx1 LassaJ, in healthy volunteers aged 18 – 55 years in the UK.

Short title: ViTaL01: A study of a new vaccine against Lassa fever in adults aged 18 - 55 years

Study acronym: ViTaL01 (Vaccine Trials against Lassa)

Chief Investigator: Prof Maheshi Ramasamy

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information and discuss it with others if you wish. If there is anything that is not clear or if you would like more information, please ask us.

What's the purpose of this research?

We are testing a new vaccine called ChAdOx1 LassaJ to check it is safe and helps the body's immune system fight Lassa fever. Lassa fever is caused by a virus spread by rodents and can result in serious illness, severe bleeding and even death. The virus poses a threat to approximately 59 million people living in West Africa, and there are currently no licensed vaccines or treatments for it. We have developed our new vaccine using the same "ChAdOx1" technology used to make the Oxford-AstraZeneca COVID-19 vaccine. We want to make sure the vaccine is safe and see how the body responds to it. This is the first time the vaccine has been tested in humans.

Who can take part?

We want to recruit 31 people between 18 and 55 years who are in good health without any serious ongoing medical conditions. Your participation is important to help us understand the vaccine's effects in healthy individuals. A full list of inclusion and exclusion criteria can be found on page 17.

Do I have to take part?

No, participation is entirely voluntary.

- You can ask questions about the study before deciding whether to take part.
- It is your choice whether to participate or not, and if you agree to take part, you can withdraw at any time
- Declining to take part or withdrawing from the study will not have any effect on your clinical care or legal rights

What will happen if I decide to take part?

If you decide to participate, your involvement will last approximately **one year** and will include:

- **Online screening questionnaire:** You will be asked to provide some basic information including contact details and answer some questions about your medical and vaccination history. You will also be asked for your consent for us to access your medical records to confirm your eligibility. If you are deemed ineligible based on any of the replies you give to these questions, the questionnaire will stop at this point. If you are eligible based on these questions, you will be asked to give consent for us to record and store your personal information and medical history, as well as for us to access your GP or NHS medical records to assess your eligibility. If you are not eligible, based on your medical records, you will be informed by the study team.

  If you are unable to complete the online questionnaire, you can communicate directly with the study team by phone or email. If you seem eligible to take part, the study team will invite you to attend a screening visit in person.

- **Screening Visit:** This is the first visit where we check if you can take part in the study, and will take around 90 minutes. Before we do anything, we will talk to you about the study and let you ask any questions you might have. After hearing about the study, if you are happy to take part, we will ask you to sign a consent form. After that, we'll ask questions about your health, do a physical check-up, take blood samples (including tests for HIV, hepatitis B and hepatitis C) and do a pregnancy test, if appropriate. If we find you are eligible to take part, we will invite you back for the visits below. If after the screening visit you are not eligible to take part, we will retain your personal information securely on our screening logs. For more information on how we store your data, please refer to the "What will happen to my data?" section on page 9.

- **Hearing tests**: You will receive a type of hearing test, called pure-tone audiometry, as part of the screening process. This involves wearing headphones and pressing a button

  every time you hear a sound. An audiologist may also physically examine your ears. If you are found to have hearing loss, you won't be able to take part in the study. The

  same hearing test will be conducted at the end of the study, and also if you develop any symptoms of hearing loss during the study. The tests take about 30 minutes and are painless. With your consent, we will refer you to an NHS clinical audiology service if any abnormality is found.

- **Vaccination Visits**: These take around 90 minutes. Everyone in the study will receive two injections in their arms, 3 months apart. You will receive two injections of either:
  - The ChAdOx1 LassaJ vaccine
  - A placebo injection which is sterile salt water only

- **Symptom eDiary:** After each injection of vaccine or placebo, you will be asked to complete a daily online symptom diary for 7 days (including the day of vaccination). This will use online data collection software called REDCap, and can be accessed through a link emailed to you. Filling this in is essential so that we can make sure you're safe. A paper diary will also be provided as a backup in case the online REDCap system is not working, however you should try to use REDCap first. You will be provided with a thermometer to take your temperature every day and a ruler to measure any swelling or redness at the injection site. This will be explained again at the vaccination visits.

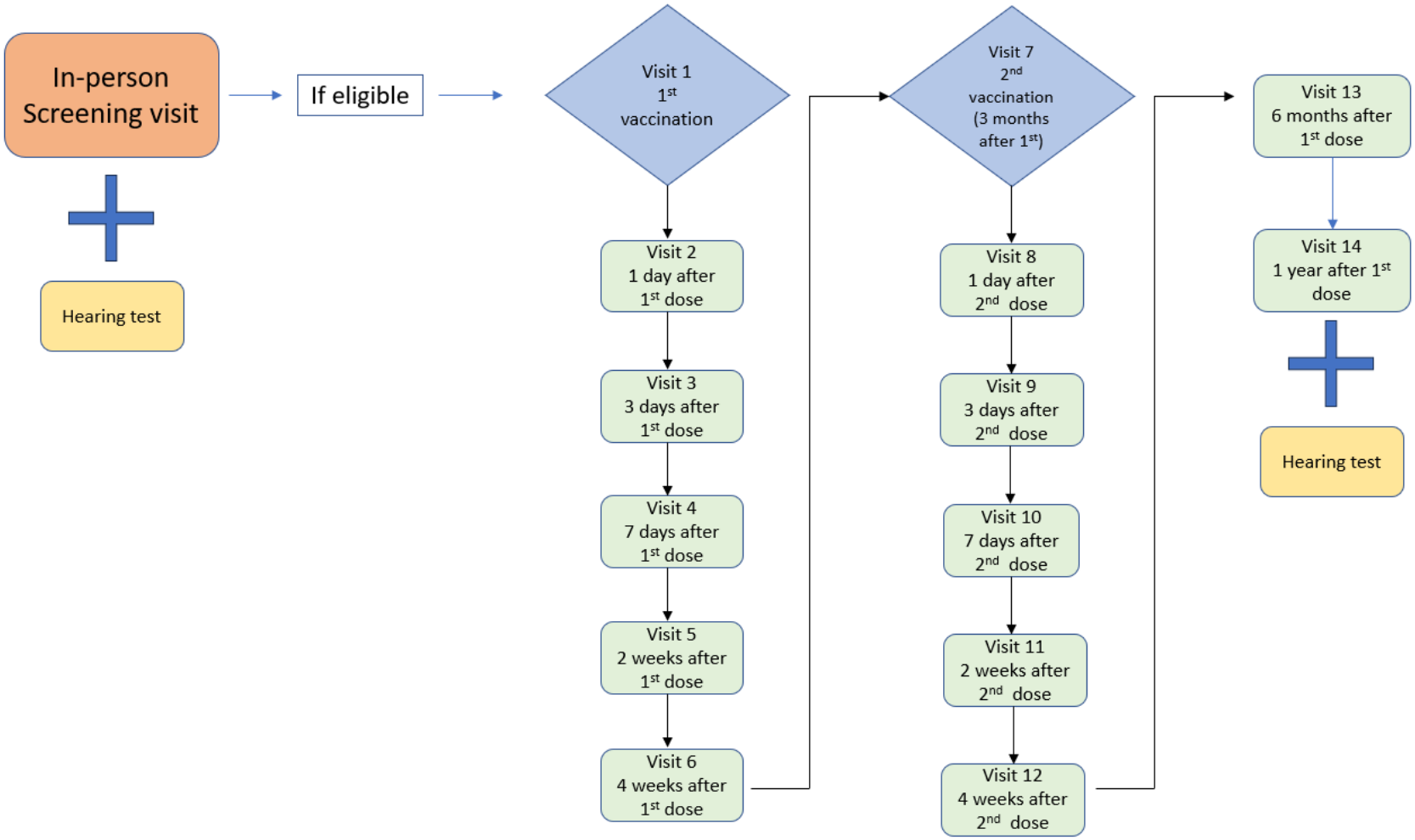
- **Follow-Up Visits**: You will attend several follow-up visits over the course of one year to monitor your health and collect blood samples. These take about 30 minutes. They are to assess the vaccine's safety and your immune response. A summary of the visit schedule is shown below.

- **Unscheduled Visits:** Occasionally we may ask you to attend an additional visit outside the main schedule. This would only be for safety reasons, for example to repeat a blood test or check up on a medical problem.

The full schedule of study visits can be found on page 4.

Oxford Vaccine Group
University of Oxford
Centre for Clinical Vaccinology and Tropical Medicine,
Churchill Hospital, Headington, Oxford OX3 7LE
Telephone: 01865 611400 info@ovg.ox.ac.uk
www.ovg.ox.ac.uk

Schedule of study visits



Where will study visits take place?

All study visits except for the hearing tests will take place at the Centre for Clinical Vaccinology and Tropical Medicine (CCVTM), Churchill Hospital, Headington, Oxford, OX3 7LE. The hearing tests may also take place at CCVTM, or alternatively at James Hearing Ltd, Oxford House, Parkway Court, John Smith Drive, Oxford, OX4 2JY.

Study Groups:

The first 6 participants to be vaccinated (cohort 1) will all be given two doses of the ChAdOx1 LassaJ vaccine. This is a safety group, and we will wait 7 days after these participants have been vaccinated before vaccinating anyone else. After that the remaining 25 participants in the study (cohort 2) will be randomly assigned by a computer to one of two different groups:

- **Group 1:** Two doses of the ChAdOx1 LassaJ vaccine (20 participants)
- **Group 2:** Two doses of a placebo (salt water) injection (5 participants)

A placebo is something that looks like a real treatment but doesn't have the same effect. It's often used in vaccine studies to see how much of a person's response is due to the treatment itself versus their belief that it's working. In this case, the placebo is sterile saltwater containing no active ingredients. These 25 participants will not be told which group they have been assigned to until the end of the study (approximately one year following their first vaccination), to reduce the risk of bias. The staff working on the study (other than those who administer the vaccine) will also not know which group these participants are in, and will only be able to confirm allocation after the study has ended.

Study samples

We will collect around 40-62 mL (8-12 teaspoons) of blood at each vaccination and follow-up visit. The total amount of blood collected over the course of the study is less than if you were to regularly donate blood at the time intervals recommended by the NHS. However, you should not also donate blood to the NHS whilst you are participating in the study. You can start donating blood again once the study has finished.

If you are able to become pregnant, we will collect urine samples throughout the study to test for pregnancy. These tests will be performed during the visit and results will be available immediately.

Other information we collect

At your screening appointment, we will ask for your National Insurance or passport number. This is to register you on The Over-volunteering Prevention Service (TOPS), which helps prevent volunteers from taking part in too many clinical studies. These details will also be stored at the study site for the duration of the study. Only staff at Oxford Vaccine Group and other medicines research units can access the TOPS database. If you receive a dose of

the study vaccine, these details will be retained in TOPS indefinitely. If you do not receive a dose, we will remove your registration from TOPS.

What else should I consider?

Contraception and pregnancy

The vaccine has not been tested in pregnancy yet so people who are able to become pregnant will be required to use contraception and have pregnancy tests before and during the study. Acceptable forms of contraception include “the pill”, “the coil” or using barrier methods (e.g. condoms).

Male participants with female partners are not required to use contraceptive methods.

Taking medications during the study

If you begin taking any new medications (prescribed or over the counter) during the study, please make a note of these and inform the study team at your next visit.

Other vaccinations during the study

If during the study you require any vaccinations for health, travel, or occupational reasons, you should inform the study team beforehand. We ask you not to receive any vaccines within 30 days (before and after) of receiving each study vaccine. The exceptions for this are flu and some COVID-19 vaccines. You may receive these as long as they are given at least 14 days before or after each study vaccine.

Private medical insurance

If you have private medical insurance or travel insurance, participation in a study will often not affect your cover for any conditions unrelated to the study, but to be certain you must tell your insurance provider beforehand if you are planning to participate.

New medical findings

During the study or screening visit, we might find something about your health that you weren’t aware of. If we find a new health issue, we will talk to you about it and, with your permission, arrange for this to be followed up by your GP. The only exception to this is if you are found to have hepatitis B or C. The law in the UK means that healthcare professionals are obliged to report new suspected cases of hepatitis B or C to the UK Health Security Agency, including personal contact information. It's important to note that due to UK reporting requirements you cannot opt out of this.

Taking part in other research studies

You should not take part in other clinical studies where drugs or vaccines are administered whilst participating in this study. You should also not take part in studies that involve repeated blood sampling while you are participating in this study.

Are there any risks in taking part?

This study involves some potential risks, and you should think carefully about these before deciding to take part. Although similar vaccines have been used before, including the Oxford-AstraZeneca COVID-19 vaccine, the vaccine in this study has not been tested in humans before. This is different to vaccines that you have had in the past for your own health, which would have been tested in thousands of people or more.

Possible vaccine side effects or risks:

- **Local reactions:** Mild discomfort at the injection site, such as pain, redness, swelling, itchiness, or warmth. These symptoms usually resolve within a few days.
- **General reactions:** Flu-like symptoms such as fever, chills, fatigue, headaches, muscle aches, joint pains, nausea, and feeling unwell may occur in the first 24–48 hours after vaccination.
- **Rare but serious reactions:** The vaccine in this study was made using similar technology (ChAdOx1) to the Oxford-AstraZeneca COVID-19 vaccine. The COVID-19 vaccine was safe in the vast majority of people who received it. However, in a few cases, it was linked to serious reactions that could result in death or serious illness. These include:
    - A rare blood clot disorder (vaccine-induced thrombocytopenia and thrombosis). This was reported following 1 in every 100,000 doses of the Oxford-AstraZeneca COVID-19 vaccine given in the UK. It can be associated with serious blood clots including in the brain. Of people who developed this very rare disorder, 1 in 5 unfortunately died.
    - A condition with low blood platelets which can be associated with bleeding (immune thrombocytopenic purpura). This is extremely rare, with only a few cases associated with the Oxford-AstraZeneca COVID-19 vaccine reported.
    - Capillary leak syndrome, a serious condition causing low blood pressure and swelling in the limbs and body. This occurred following less than one per million doses of the Oxford-AstraZeneca COVID-19 vaccine.
    - Severe allergic reactions, which are extremely rare but can be life-threatening

- Serious neurological conditions that can result in paralysis, weakness, confusion, seizures or other disability. A very small number of cases occurred following vaccination with the Oxford-AstraZeneca COVID-19 vaccine, but it is unknown if the vaccine caused them.

We do not know whether these rare reactions may occur with the vaccine in this study, however because it is similar to the Oxford-AstraZeneca COVID-19 vaccine we will be monitoring closely for any signs of them. You should seek immediate medical attention if you develop any of these symptoms in the first 28 days following vaccination:

- Sudden severe headache that does not improve with usual painkillers or is getting worse
- An unusual headache which seems worse when lying down or bending over, or may be accompanied by blurred vision, nausea and vomiting, difficulty with speech, weakness, drowsiness or seizures
- New and unexplained pinprick bruising or bleeding
- Shortness of breath, chest pain, leg swelling or persistent abdominal pain
- Feeling faint due to low blood pressure

You will be provided with a medic alert card with study mobile number, which has 24/7 access to a study doctor. If you experience any of the above events or are in any way concerned, you should call this number. We advise you to carry the medic alert card with you throughout the study and you may use this to show medical staff that you are taking part in this study.

- **Hearing tests:** Lassa fever itself can cause significant hearing loss in people who have been infected. It is unknown why this happens. There is no indication that the ChAdOx1 LassaJ vaccine will cause hearing loss, however, to be absolutely sure we are conducting hearing tests before and after the study. If you develop any change in your hearing during the study, you should inform the study team as soon as possible.
- **Unknown or unexpected side effects:** With any new medicine or vaccine that is in early development there is always a possibility of a previously undescribed or unexpected side effect occurring. This could include something severe. If you experience anything that is unexpected (i.e., not mentioned in this information sheet), you should phone the 24-hour study contact number and speak to a study doctor.

Other risks:

- Blood sampling may cause slight pain, bruising, or occasionally light-headedness or fainting.

- There is no risk of catching Lassa virus from the vaccine in this study.

What are the benefits of taking part?

By taking part in this study, you'll be helping to develop a vaccine against Lassa fever, which could protect people in West Africa in the future. However, you will not get any direct benefit by taking part in this study. We do not yet know whether the new vaccine will work so you should not assume that you have any protection against Lassa fever if you are vaccinated.

Will my GP be notified of my participation in the study?

If we need to request your medical records or if it affects your clinical care, we may notify your GP of your involvement in the study. Sometimes GPs may be contacted to follow up findings that may be of clinical significance, such as high blood pressure or indications of depression. This would always be done with your permission only.

Will my taking part in this study be kept confidential?

Yes. All study records and samples will be identified only by a code. We will only use your name, date of birth and NHS number where this is necessary, for example to link to your NHS records or to contact you. Information that can identify you will be securely and only held by Oxford Vaccine Group staff for the purposes of the study.

Confidentiality will be maintained as far as it is possible, unless you tell us something which implies that you or someone you mention might be in significant danger of harm. In this case, we would have to inform the relevant agencies, but we would discuss it with you first.

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.

What will happen to my data?

Data protection legislation requires that we, the University of Oxford (whose legal name is The Chancellor Masters and Scholars of the University of Oxford), 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 is the sponsor for this study and is responsible for looking after your information and using it properly.

We will need to use information from you from your medical records, your GP, and/or your hospital records for this research project. We will share your information related to this research project with the following types of organisations:

• Local NHS laboratories as part of processing the clinical safety blood samples (please see page 12)

This information will include your initials, NHS number, name, home address/contact details, email address. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure by:

• Data will be collected and held by the Oxford Vaccine Group. It will be accessible to staff at the Oxford Vaccine Group, responsible staff from the University of Oxford who may monitor/audit the data collection process, and inspectors from ethics.

• The University of Oxford Data management and IT Team will be able to view your email address, which is necessary for the eDiary to function.

• Storing in secure database servers held by the University of Oxford.

We may share data about you outside the UK for research related purposes to:

• For analysis by collaborating research groups

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

• Academic institutions such as universities

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

• (some of) the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK.

• we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website (https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/)

• We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says.

• We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing.

• We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website (https://ico.org.uk/for-organisations/report-a-breach)

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We will keep your study data for the minimum period of time required by:

• 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.

• Research data (anonymised) will be stored for at least 99 years. If you only complete online screening (i.e., before you give informed consent) your data will only be kept to the end of the study.

• 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 be destroyed. If you agree to future contact (e.g., to be informed of other studies) your contact details will be held separately from the study data and you can request at any time to have your details removed.

• Your national insurance or passport number for "TOPS Database Registration" and payment processing will be taken at the screening visit. We will securely retain copies until the end of the study. Your bank details will be stored for 10 years after the project ends in line with the University of Oxford's financial policy.

• Some of the de-identified research data may be made available in open, online research databases. Sharing the results of the study in this way means it can continue to contribute to scientific progress in future.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records / your hospital / your GP. If you do not want this to happen, tell us and we will stop. (Also see page 13 - What happens if I don't want to carry on with the study?).

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK by:

- asking one of the research team at info@ovg.ox.ac.uk
- sending an email to info@ovg.ox.ac.uk
- calling us on 01865 611400
- contacting the University's Data Protection Officer data.protection@admin.ox.ac.uk
- looking at the University's privacy notice available at: https://compliance.admin.ox.ac.uk/research-data

If you would like to find out more about the use of confidential data in research, the HRA has developed a general information leaflet which is available at: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/

What will happen to my samples?

With the exception of clinical safety blood samples, which are sent to local clinical laboratories and follow local sample labelling requirements (typically including the participant's medical record number (MRN), NHS number, name, sex and date of birth), your samples will be assigned a code and will only be identifiable by this code. This means that any samples sent to laboratories for processing or given to researchers outside of the study clinic (except for the safety blood samples) will not have information that identifies you. However, as your DNA is unique, samples can never be completely anonymous. We will collect blood samples throughout the study to check your health and see how your body

immune system is reacting to the vaccine. These will be analysed in the Oxford Vaccine Group, University of Oxford research laboratories and local clinical laboratories. We may also send blood samples to other researchers working with us on this research project. This may include researchers in other countries outside of the UK, including in commercial laboratories.

If you are able to become pregnant, we will collect urine samples throughout the study to test for pregnancy. These tests will be performed during the visit and results will be available immediately. Urine samples will then be destroyed immediately after testing.

If you choose to take part in this study, we will be asking for your separate permission to store your samples (including cells and DNA) after the end of the study, in a collection of samples called the Oxford Vaccine Centre Biobank. Details of this will be provided in a separate booklet after you are enrolled into this study, and you are free to say no to the Biobank and continue to take part in this study if you wish. If you decline to take part in the Biobank, all of your leftover samples, including those shared with other researchers, will be destroyed 12 months after the last participant has completed the ViTaL-01 study. The Biobank has been previously approved by a Research Ethics Committee (South Central – Hampshire B, reference 21/SC/0161).

Will any genetic tests be done?

We will do genetic tests on your blood samples to look at the patterns of genes that regulate your own individual immune response. These are called Human Leukocyte Antigen (HLA) genes. This will help us to work out which aspects of the immune response to vaccines are due to genetic differences between individuals. We may also try to identify and study the genes that appear to be important in your immune response to the vaccination. You will not receive the results of any genetic tests performed.

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

You are free to withdraw from the study at any point, and you don't have to give a reason. If you have received a vaccine, we may ask if we can follow you up for safety reasons only. Again, this is entirely up to you.

If you withdraw from the study, unless you request otherwise, any blood or tissue samples collected to that point will be used for research as detailed in this participant information sheet. You are free to request that your blood or tissue samples are destroyed unless they have already been analysed. Any data we have collected up to this point would also be included in our analysis.

How much will I be reimbursed if I take 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 the whole study is up to £1,570. You will be compensated £110 for attending each of the screening and vaccination visits, £50 for audiology visits and £90 for each of the study follow-up visits.

These amounts are based on the following figures:

- Travel expenses: £30 per visit
- Inconvenience of blood tests/sample collection: £20 per blood donation
- Time required for visits: £60 per screening or vaccination visit, £40 per follow-up visit, £20 per audiology visit
- Diary card completion: £30 per fully completed diary

You may also receive reimbursement for any unscheduled visits you attend. You would be reimbursed £90 per unscheduled visit, or £50 if it is an unscheduled audiology visit.

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 is not taxed and should not affect any benefits you receive.

Reimbursements will be made following the screening hearing test and after visits 6, 12 and 14 (including a final hearing test). It can take up to 6 weeks for a payment to reach your bank account following a visit that triggers reimbursement. Payments are made directly by bank transfer. For this reason, we require participants to provide their bank details at the screening.

What will happen to the results of the study?

Results from this study may be published in scientific journals or presented at medical conferences. This can take several years following the end of the study. Your individual results would not be identifiable, nor would you be identified in any report or publication. We will provide a summary of the results and a link to the publication via email when they are available.

The anonymised data from this study will be shared with the collaborating partners who are organising and funding this research work. These partners may be based outside the UK. As this data is anonymised, it may be stored indefinitely. 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 an MD or PhD, and to support research in the future, here or abroad.

What if there is a problem?

If you have a concern about any aspect of this study, please speak with the study team using the contact details below. They will do their best to answer your questions.

The investigators recognise the important contribution that volunteers make to medical research and will make every effort to ensure your safety and wellbeing. The University of

Oxford, as the study sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. 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 doctors can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary.

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, contact the research investigators and the Chief Investigator at info@ovg.ox.ac.uk or 01865 611400, or you may contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) office at rgea.complaints@admin.ox.ac.uk or on 01865 616480.

How has the public been involved in this study?

Lay members of the public were involved in reviewing and editing this Participant Information Sheet and other study documents.

Has the study been reviewed by regulatory and ethics committees?

Yes, this study has been approved by the UK Medicines & Healthcare products Agency (MHRA) and by the London - Riverside Research Ethics Committee

Who is organising and funding this study?

This study is part of the ViTaL (Vaccine Trials against Lassa) programme of work and is sponsored by the University of Oxford. It is organised by the Oxford Vaccine Group, which is

part of the University of Oxford. The Chief Investigator is Professor Maheshi Ramasamy. If we ask your GP for a summary of your medical history, we will pay them £20 for this service. The study is funded by the Coalition for Epidemic Preparedness Innovations (CEPI).

Will I be contacted about other studies?

If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form securely until such time as your details are removed from our database. We will keep the consent form and your details separate from one another and any research data. If you do agree to be contacted, all contact will come from the Oxford Vaccine Group in the first instance. Agreeing to be contacted does not oblige you to take part in any future research, and you can ask to have your contact details removed

from this register at any time. Your contact details would be held securely on a password-protected university server accessible only to authorised Oxford Vaccine Group staff.

Further information and contact details

We hope this information sheet has given you enough information to make a decision on whether to volunteer for this study. If you would like further information about participating in research, please visit the following website: https://www.nhs.uk/tests-and-treatments/clinical-trials/

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 pre-screening questionnaire at: https://apps.ovg.ox.ac.uk/redcap/surveys/?s=XK94YPMPLJCEPTWD

If you have further questions about the study that you would like to discuss with our team, please contact us at:

Email: info@ovg.ox.ac.uk

Tel: 01865 611400

Oxford Vaccine Group, University of Oxford
Centre for Clinical Vaccinology & Tropical Medicine (CCVTM)
Churchill Hospital, Oxford, OX3 7LE

Changes to this information sheet

This is a new version of the participant information sheet. Previously this information sheet said that we would take around 40 – 52mL of blood at each visit, however we have increased this volume to

40 – 62mL. This volume is still less than the maximum amount of blood you could donate to the NHS over the same time period.

Full list of inclusion and exclusion criteria

You must:

Be aged **18 to 55 years**
Be in **good health**
Be able to **attend all scheduled visits** and **comply with all study procedures**, including having internet access for the completion of electronic symptom diaries
Be willing and able to give **informed written consent** for participation in the study
Be willing to allow us to check your **past medical and vaccination history** and **view your medical records**, and be willing for us to notify your GP of your participation in the study
Be willing to provide your **national insurance number or passport number** to be registered on The Over-volunteering Prevention Service (see page 5 for more details)
Agree to **not give a blood donation** during the course of the study
For people who are able to become pregnant only: Use **effective contraception** for the **duration of the study** (see page 6 for details) *and* have a negative pregnancy test at the screening and vaccination visits

You must not have:

Current and Past Medical Problems
A **serious or severe long-term illness**, e.g. a condition which requires hospital admissions or affects your daily life
A previous history of suspected or confirmed **Lassa virus or arenavirus infection**
Received a **blood transfusion** or **immunoglobulin treatment** within 3 months of the first vaccination
Any known condition **affecting your immune system**, e.g. HIV infection, immunodeficiency syndrome
A history of **allergy or anaphylaxis** to vaccines
A history of **angioedema**
A history of **cancer** (except some skin cancers)
A **serious ongoing mental health condition** if this may affect your participation in the study

A history of **bleeding disorders, blood clotting disorders or major blood clot** (e.g. clots in the brain, legs or lungs)
A history of **capillary leak syndrome**
A history of **Guillain-Barre syndrome, transverse myelitis or other neuroinflammatory syndromes**
Current **alcohol abuse**
A history of **injecting recreational drugs** within 5 years of the study start*
A history of **hepatitis B or hepatitis C infection**
A history of **sensorineural hearing loss**
Other Vaccines: You must not
Have received **any ChAdOx vaccine** in the 6 months before the first study vaccination Receive **flu or COVID-19 vaccines within 14 days** (before or after) of each study vaccine. This extends to **30 days for any other vaccine**.
Other Clinical Studies: You must not
Participate in **another clinical study** that involves receiving a drug or vaccine, or in which significant amounts of blood were taken, in the **12 weeks before the first study vaccination** and for the duration of the study
(In people who are able to become pregnant only) You must not
Become **pregnant or breastfeed** during the study, or plan to become pregnant
You must not
Have travelled to a Lassa Endemic Country in West Africa within 12 months prior to enrolment or intend to travel to these countries during the course of the study
Work at the study site, or be a partner of someone who does

If you are not sure whether you can join the study, you can contact the study team to discuss further (details on page16. The criteria above will also be discussed with you in detail at the screening visit by study staff to make sure that you are eligible to take part.

*We ask about this during the screening appointment as injecting recreational drugs may affect your ability to participate in the study, or affect your immune response to the vaccine. We would not pass this information on to anyone without your consent.