Developing a vaccine against Bundibugyo ebolavirus

OXFORD VACCINE GROUP

Lead Study Location

Oxford Vaccine Group

You are invited to take part in a research study called 'Developing a vaccine against Bundibugyo ebolavirus', which is being carried out at Oxford Vaccine Group

What is this information sheet for?

Before you take part in a research study, you need to know more about the study to help you decide if taking part is the right decision for you.

In this information sheet, we will tell you:

- Why we are running this study
- What will happen during the study
- The risks and benefits of taking part
- Your rights before, during, and after the study

What if I still have questions?

If you have questions or concerns after reading this, you can contact us by phone, email or letter.

If you're not sure whether to take part, you can talk to a friend, family member, your GP or another health professional.

You can show them this information sheet.

Do I have to take part?

No. You can choose whether to take part. If you decide to join, you can leave the study at any time without giving a reason.

You can contact us at any time before, during or after the study

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Contents

Study Summary

What are you studying?	• A **new vaccine called ChAdOx1 Ebola BDBV Vaccine (Recombinant)** which is designed to work against the disease caused by **Bundibugyo Ebola virus (BVD)** • We want to find out about the **safety and tolerability** of the vaccine • We want to find out how your **immune system responds** to the vaccine
Who can take part?	People who: • are **aged 18-55** • are **generally healthy**, or have a **stable (well-controlled) long-term condition** • can **attend all study visits** over one year
You might not be able to take part if you:	You might not be able to take part if you: • are **pregnant** or are planning to become pregnant • have a **serious or unstable medical condition** • have had a **severe allergic or other serious reaction to vaccines** • have been previously given an **Ebola vaccine** for any reason • have been previously given a **ChAdOx1 or ChAdOx2**-based vaccine (including the Oxford/AstraZeneca COVID-19 vaccine) • have previously had a confirmed or suspected **Ebola** virus infection or travelled in the last 6 months to an area where there is Ebola virus • are taking part in another **clinical trial.** • See page 10 for more details.
Will I be paid?	No, however you will be reimbursed **up to** £1200 for your time and inconvenience. This amount may be lower if you receive a lower number of doses in the study. See page 24 for more details

Where will study visits happen?	Study visits will be at Oxford Vaccine Group, Oxford.
How much time will it take?	There will be up to **11 visits** (and a screening visit) depending on which cohort you are in, over 12 months.
What procedures are used?	• Attend a **screening visit** to check if you can take part. • In the **first phase** of the study: • The first 10 people will have **one dose** of the ChAdOx1Ebola BDBV Vaccine (Recombinant) • The next 40 people to be enrolled will be chosen at random to be given **one dose** of the **ChAdOx1 Ebola BDBV Vaccine (Recombinant)** or a **placebo (more details on page 16)** • In the **second phase** of the study, the first 10 people from the first phase will receive a booster dose of the **ChAdOx1 Ebola BDBV Vaccine (Recombinant)** 6 months after their first dose • We will take blood samples from you at each visit • You will have a pregnancy test (if applicable) before each vaccination and at the end of the trial • You will complete a short **online symptom diary** for 7 days after each vaccination
Are there risks to taking part?	• This is the **first time** this vaccine has been given to humans, because of this, **we do not yet know all the possible risks and side effects.** • You may have short-lived symptoms after vaccination, such as mild discomfort in your arm and fever. • **Blood tests** may cause slight pain, bruising or feeling faint. • **Very rare but serious reactions** have been seen with similar vaccines. • Full information about these risks and side effects can be found on pages 20-24
Are there benefits to taking part?	You will not directly benefit from taking part. However, your participation may help to protect others in the future by contributing to advances in vaccine development. You should not assume you will be protected from Bundibugyo Ebola virus disease (BVD) in the future if you take part in the study.

Introduction to the study and why this research is needed

Bundibugyo virus (BVD) is a member of the Ebola virus family and can cause a serious illness known as Bundibugyo virus disease or **BVD**. People can become infected through contact with infected animals or through direct contact with the bodily fluids of someone who already has the disease. The disease can spread quickly during outbreaks, particularly in healthcare settings (like hospitals) and among people close to those who are already infected.

BVD was first identified during an outbreak in the Bundibugyo district of Uganda in 2007-2008. Symptoms of BVD often begin with fever, tiredness, headache and muscle aches. As the illness progresses, people may develop vomiting, diarrhoea, abdominal pain and, in severe cases, bleeding, organ failure and death. Previous outbreaks have had a high fatality rate.

On the 15th May 2026, a new outbreak of BVD was confirmed in Ituri Province, Democratic Republic of the Congo (DRC), and then a further case was reported in Uganda. On the 17th May 2026, The World Health Organization (WHO) recognised the recent outbreak as a serious international public health concern.

There are currently no approved vaccines for BVD, which are urgently required to help control the current and future outbreaks.

We are testing a new vaccine for BVD, called ChAdOx1 Ebola BDBV Vaccine (Recombinant). This study is the **first time the ChAdOx1 Ebola BDBV Vaccine (Recombinant)** will be given to people. The vaccine has been developed by researchers at the University of Oxford using the same vaccine platform that was used to create the Oxford/AstraZeneca COVID-19 vaccine.

The vaccine will be made by Serum Institute of India, Private Limited (SIIPL).

This vaccine technology has been studied extensively in many thousands of people worldwide and has been studied for a range of infectious diseases. Two billion doses of the similar ChAdOx1 based COVID-19 vaccine developed by the University of Oxford and AstraZeneca have been sent around the world to more than 170 countries.

The main aim of this study is to find out whether the **ChAdOx1 Ebola BDBV Vaccine (Recombinant)** is safe and well tolerated in healthy adult volunteers. The study will also look at how the body's immune system responds to the vaccine by measuring immune responses in blood samples. These early results will help researchers understand whether the vaccine has the potential to protect against Bundibugyo virus

infection. As well as the UK, there will be a similar study in a region directly affected by BVD.

The knowledge gained from this research could support the development of a vaccine that may help protect healthcare workers, outbreak response teams, and people living in regions at risk of BVD outbreaks. This work will also contribute to world-wide efforts to improve preparedness for future infectious disease emergencies and strengthen international health security.

Who are we?

Your study visits will take place at Oxford Vaccine Group

Researchers at **The University of Oxford** have been studying infections using healthy volunteers for decades to provide **world-leading research** in infectious diseases. We have a large amount of experience in running clinical studies and trials like this.

Study Sponsor	**The University of Oxford** The Sponsor is the organisation that takes overall responsibility for the study	ox.ac.uk/research/support/about-research-services
Study Location	The study is taking place at several different locations. This information sheet is for this study location. Your study visits will take place at: **Oxford Vaccine Group** Churchill Hospital, Annexe Reception, Centre for Clinical Vaccinology and	ovg.ox.ac.uk

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Principal Investigator (PI)	**James Gilchrist** The researcher responsible for the conduct of the research by the team at this study location	ovg.to/t/james-gilchrist
Chief Investigator (CI)	**Katrina Pollock** The lead researcher for the study who is responsible for the overall conduct of a research project at all study locations	ovg.to/t/kat-pollock
Funder	**Coalition for Epidemic Preparedness Innovations (CEPI)** A funder provides money and/or resources needed to run the study	cepi.net

The Study in Detail

What is the vaccine being tested in this study?

The vaccine being tested is called **ChAdOx1 Ebola BDBV Vaccine (Recombinant)**.

This trial vaccine has been developed by researchers at the University of Oxford.

ChAdOx1 Ebola BDBV Vaccine (Recombinant) is an investigational vaccine, which means it is still being studied and has not yet been approved for general use. This study is the first time the vaccine will be given to people, and an important aim of the research is to learn more about its safety and the immune responses it produces.

The vaccine is very similar to the Oxford/AstraZeneca COVID-19 vaccine. However, the trial vaccine targets a part of the **Bundibugyo** virus rather than a part of the virus that causes COVID-19.

The vaccine is developed through genetic engineering using a weakened chimpanzee adenovirus, a harmless version of a common cold virus.Millions of people around the world have received vaccines based on this technology, providing researchers with extensive information about how the platform works and information about its safety.

The vaccine does not contain the whole Bundibugyo virus and cannot cause Ebola virus disease.

More information on how vaccines are made is available at on the Vaccine Knowledge website (vaccineknowledge.ox.ac.uk).

While no vaccine specifically targeting Bundibugyo virus has yet entered clinical trials, our study team have gained considerable experience from vaccines developed against other Ebola viruses, including Zaire and Sudan Ebola viruses, as well as from a large number of studies of ChAdOx1-based vaccines. This existing knowledge has helped inform the design and development of ChAdOx1 Ebola BDBV Vaccine (Recombinant). See the next section for more information.

This study will involve two different cohorts (groups) of participants:

- The **first 10** participants **will all** receive **one dose** of the ChAdOx1 Ebola BDBV Vaccine (Recombinant) so that researchers can closely monitor its safety.

  The next **40 participants** will then be chosen by computer at random to receive **one dose** of either the **ChAdOx1 Ebola BDBV Vaccine (Recombinant) or a placebo** (a saltwater injection that contains no active vaccine). The clinical team cannot influence which will be given. This cohort will not be told whether they are

receiving the vaccine or the placebo. This is called being **blinded**. Participants will find out at the end of the study what was received, once all participants have finished their visits.

- The first 10 participants will also receive a **booster dose** 6 months after their first dose

This vaccine will be given as an injection in the muscle near the top of the non-dominant arm (for instance, if you are right-handed, it will be given in your left arm).

Researchers will carefully monitor any side effects, symptoms or changes in health that occur after vaccination and determine how well participants tolerate the vaccine. They will take blood tests to measure the immune response to the study vaccine.

Can I take part in the study?

To be able to take part in the study, the following **must apply** to you**:**

General Requirements

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
- have internet access to complete 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 **tell your GP** that you are taking part 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 **not to donate blood** during the study
- use highly effective contraception while you are in the study if you are able to become pregnant (see page 6 for details)
- have a negative pregnancy test at the screening and vaccination visits if you are able to become pregnant

Current and Past Medical Problems

You must not have:

- a **serious or severe long-term illness**, e.g. a condition which requires hospital admissions or affects your daily life
- had a suspected or confirmed **Ebola virus infection** at any time in the past
- received a **blood transfusion or immunoglobulin treatment** in the 3 months before the first vaccination
- any known condition affecting your **immune system**, e.g. HIV infection, immunodeficiency syndrome
- had an **allergic reaction to vaccines** at any time (anaphylaxis)
- had **angioedema** at any time
- had **cancer** (except some skin cancers) at any time
- a serious ongoing **mental health condition** if this may affect you taking part in the study
- **bleeding disorders**, **blood clotting disorders** or a major **blood clot** (e.g. clots in the brain, legs or lungs) in the past
- had **capillary leak syndrome**
- had **Guillain-Barre syndrome**, **transverse myelitis** or other neuroinflammatory syndromes in the past

- had a currently **active autoimmune conditions** of any severity requiring treatment or on-going medical follow-up.

- a current **alcohol abuse** problem
- **injected recreational drugs** in the 5 years before the start of the study
- have **hepatitis B** or **hepatitis C** infection

Other requirements

You must not

- have received any **ChAdOx1 or ChAdOx2-based** vaccine in the past, including the Oxford/AstraZeneca COVID-19 vaccine
- have received an **Ebola** vaccine at any time in the past
- have **flu or COVID-19** vaccines within **14 days** (before or after) of each study vaccine
- have **any other vaccine** within **30 days** (before or after) of each study vaccine

- take part 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 vaccine** and for the whole time you are in this study
- become **pregnant or breastfeed** during the study, or plan to become pregnant
- have **travelled to a country currently experiencing filovirus outbreaks as declared by the WHO** (e.g. the Democratic Republic of the Congo and Uganda) in the 42 days before your enrolment in the study, or intend to travel to these countries while you are taking part in the study
- **work at the study location**, or be a partner or a dependent child of someone who does

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

More Information on exclusions

Pregnancy

There is no data on the use of this vaccine in pregnancy. To take part in the study, if you could become pregnant you **must** use highly effective contraception unless you:

- do not have a female reproductive system
- are post-menopausal
- have been surgically sterilised
- have complete abstinence from sex (do not have sex at all) with a male partner

Acceptable contraception methods include:

- oral, injected or implanted hormonal contraceptives that prevent ovulation, including “the pill”
- intrauterine devices (IUD)
- intrauterine systems (IUS)
- bilateral tube exclusion
- having a single male sexual partner, who has had a vasectomy
- complete abstinence from (not having) sex with a male partner.

Male participants are not required to use barrier methods for the purpose of contraception. There is no evidence that the vaccine can be shed into semen.

Pregnancy test

All participants who could become pregnant will have to take a pregnancy test at screening, before each vaccine is administered and at the final visit. You will need to take the pregnancy tests even if you are using the acceptable contraception methods required.

What will happen in the study?

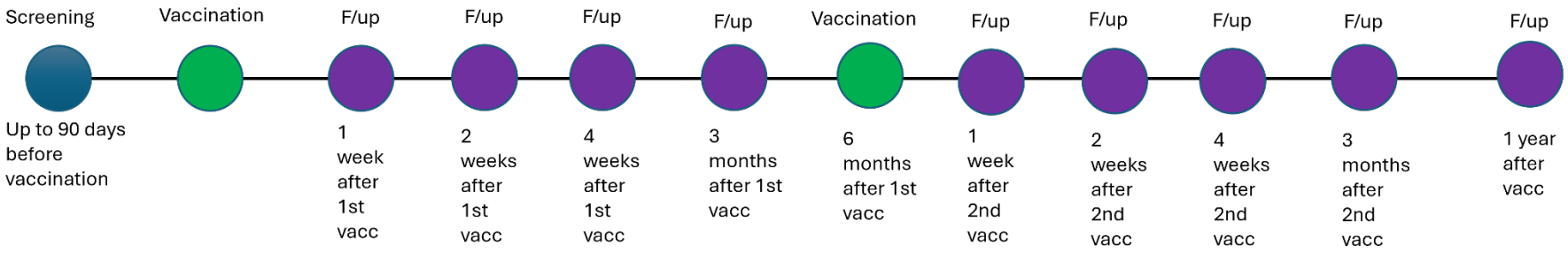
Study Timeline – Overview

The next two pages shows the study visit timelines and key procedures that may happen at each visit. Full details of what will happen at each visit are given in the following section.

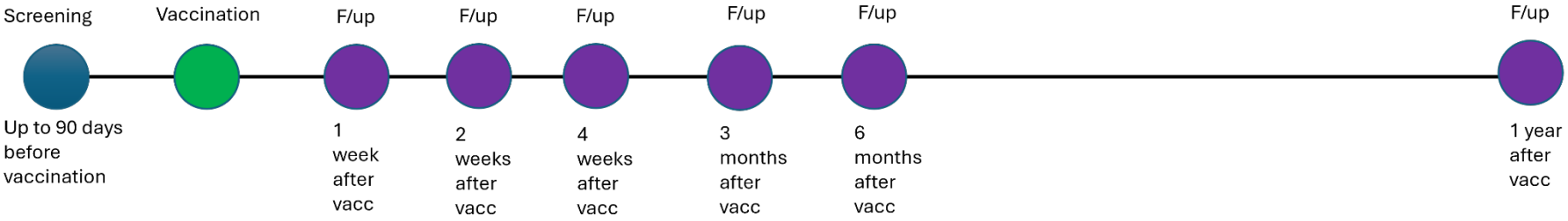
If the screening process finds you are eligible to take part, and you choose to take part, you will be involved in the study for about **12 months** in total.

At **all** visits, and in between visits, you are always welcome to ask the study team any questions you may have

Cohort 1 visit timeline:



Cohort 2 visit timeline:



Vacc = vaccination
F/up = follow-up visit

Online Pre-screening — **Before study**

- Online questionnaire
- Consent to check medical records

All participants

Screening visit — **Before study**

- Questions, Information, Consent
- Health checks
- Blood samples
- Pregnancy test (if applicable)

All participants

Vaccination visit 1 — **Day 0**

- Blood samples
- Pregnancy test (if applicable)
- Vaccination
- E-diary issued

Cohort 1
&
Cohort 2

Follow up visits — **Day 7 - 180**

- Blood samples
- E-diary review

Cohort 1
Days 7, 14, 28, and 84 (4 visits)

Cohort 2
Days 7, 14, 28, 84, and 180 (5 visits)

Vaccination visit 2 — **Day 180**

Cohort 1 only

- Blood samples
- Pregnancy test (if applicable)
- Vaccination
- E-diary issued

Follow up visits — **Day 187 - 365**

- Blood samples
- E-diary review
- Pregnancy test (final visit)

Cohort 1
Days 187, 194, 208, 264 and 365 (5 visits)

Cohort 2
Day 365 (1 visit)

Study timeline in detail

All study visits are at your local study location. The Pre-Screening Questionnaire and Electronic Diaries can be completed online at home.

Online pre-screening questionnaire and medical records consent

We will ask you to complete a Pre-Screening Questionnaire to check if you can take part. The questionnaire asks about your medical history and records your contact details. This registers your interest in the study. 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 to check your health and vaccination history
- record your contact details.

Your contact details and medical records will be kept secure and confidential. For more information, please see the 'What happens to my data?' section on page 27.

Screening Visit

(up to 2 hours)

The purpose of screening is to find out whether you can take part in the study.

At the screening visit, you will:

- discuss the study with a member of the clinical team
- ask any questions about the study you may have
- sign a consent form, if you decide to take part

We will then

- check your identity
- check your medical and vaccine history
- perform a physical examination and check your vital signs (temperature, blood pressure, and heart rate)
- take blood samples
- take a urine pregnancy test (if applicable).

Your **blood** will be checked for general health (blood count, kidney, and liver function), HIV, hepatitis B and C.

If you opt in, blood samples taken in this study may be used for research involving the creation of specific antibodies called 'monoclonal antibodies.' These are proteins made in the laboratory that help the body's immune system recognise and fight specific diseases. (This is optional, you do not have to consent to this).

You will also need to provide your **National Insurance Number** (UK citizens) or your **passport number** (non-UK citizens). This lets the team register you on **"The Over-volunteering Prevention System" (TOPS). These details will be recorded in the system.**

This is standard practice when volunteering in a research study. It acts as a safety measure to prevent volunteers taking part in more than one study at a time that when combined, may negatively impact their health due to drug interactions or having to provide multiple blood samples.

More information about The Over-Volunteering Prevention System (TOPS):

ovg.ox.ac.uk/research/tops

During your screening appointment we will also **take a photocopy of a form of ID.** This will be stored within your study records and used to check your identity at each of your study visits. Acceptable forms of ID are:

- photographic ID: Passport, Driving License, Blue Badge, Travel Passes, Proof of Age Standards (PASS) card, Defence ID card, Government Issued ID cards.
- work issued ID cards
- if NO photographic ID is available, proof of name and address such as a utility bill, bank statement, Universal Credit or Benefits Agency letter ALONGSIDE a photo taken, printed, signed and dated by the study team staff. The digital copy of the photograph will be deleted from computer files once printed.

If the study team finds any reason why you cannot take part in the study, we will talk to you about this.

Once the study team have decided that you are suitable for the study, we will let you know and arrange a date for your vaccination visit. If more than **90 days** have passed from your screening visit to vaccination, we will need to **repeat** some of the procedures from your screening visit.

Coming to the screening visit does not mean you have to take part. It is an opportunity to meet with the study staff and ask questions. You do not need to decide at the screening visit if you want to take part.

Your participation in this study is at the researchers' discretion. This means that the research team will make the final decision on who can and can't take part, based on their experience and expertise.

Vaccination day visit

(Up to 2 hours at your local study location)

We will

- ask you about any changes in health since your screening visit
- check your vital signs
- collect blood samples
- take a urine pregnancy test (if applicable)
- give you the vaccine, as an injection into the muscle of your arm

You will then be observed for at least 30 minutes by a member of the study team in case you have any immediate reaction.

Electronic Symptom Diary (eDiary)

You will be set up with a web-based electronic diary ("E-diary") where we ask you to record:

- your temperature once a day for **7 days**
- any symptoms you experience including at the site of injection **for 7 days**

You will be able to access the e-diary via a daily link that will be sent to you by email. You must tell us if you have a high temperature (38°C or above). You can take paracetamol and ibuprofen after the vaccination if you need it.

A clinical member of the study team will be checking your e-diary daily, so it is important that you fill it in regularly. We may contact you by phone if the e-diaries are not completed or not working.

We will also give you a thermometer, a ruler, a paper back-up diary, and an emergency contact card with the contact details of the study team who are available 24 hours a day.

Your e-diary access will stop after those 7 days, but **for 28 days** following your vaccination you should still let the study team know about any other symptoms and illnesses you may experience even if you think they are not related to the study. You can let the team know using the 24-hour study contact number provided, or at your study visits.

After 28 days following your vaccination and **until the end of the study**, you should still let the study team know about any other symptoms and illnesses you may experience if you have had to seek medical attention for them.

Follow up visits

(Up to 30 minutes each, at your local study location)

After the vaccination you will attend the study location for short follow-up visits.

At these visits we will:

- ask you about any symptoms or illnesses that you have had
- review your electronic symptom diary
- take blood samples
- record your vital signs
- Take a urine pregnancy test (final visit)

You may be asked to attend additional visits for safety reasons (for example, if you become unwell and need an in-person review or if there are abnormalities (unusual results) on your blood tests that require repeating).

If you cannot attend a scheduled visit, please contact the study team as soon as possible. We will help you reschedule.

What samples will be collected?

We will take blood samples to help us generate safety and immunology data.

Blood sampling

The total volume (amount) of blood taken will not be the same for every participant. This is because different cohorts have different numbers of visits. A maximum of around 730 mL of blood will be taken over the study period of 12 months. As a comparison, if you donate blood to the NHS Blood Service a woman would be able to give a maximum of 1410 mL per year over three visits, and men 1880 mL per year over four visits.

Because of the amount of blood taken during the study, participants will be asked **not to donate any blood while participating in the study** for their own safety

Under current UK regulations, you must not donate blood during your involvement in the study. You will be able to donate blood again after you have completed the study, but you should tell the Blood Service that you took part in this study.

Are there any risks from taking part in this research?

Although the study is moving forward quickly to address the current BVD outbreak, all the required safety checks, ethical reviews, and regulatory approvals have been completed before volunteers receive the vaccine.

The timeline has been shortened by dedicating more people, funding, and resources to the project—not by cutting corners. The same safety standards apply as they would for any vaccine study. **No safety steps have been removed.**

Risks of vaccination

Because ChAdOx1 Ebola BDBV Vaccine (Recombinant) has not been given to people before, there may be side effects that are not yet known. One of the main purposes of this study is to monitor participants closely so that researchers can better understand the safety and tolerability of the vaccine.

Based on experience with other vaccines that use the ChAdOX1 platform, the most common side effects include

- Headache
- Fatigue
- Fever (High Temperature)
- Feeling generally unwell
- Muscle aches
- Joint pain
- Redness, swelling and/or tenderness at the site of injection

Side effects may be mild or severe. Most effects will stop shortly after receiving the vaccine.

Rare but serious vaccine 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 first 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.

Research is ongoing to understand better why these rare but serious reactions happen. 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

If you were to experience any of the above, or anything else that is unexpected (i.e. not mentioned above), you should phone the 24-hour study contact number and speak to a study doctor.

We will monitor everyone in the study for any side effects, particularly in the first seven days after receiving a vaccine. This is done by completing the electronic diary (e-diary) as mentioned on page 19. This electronic diary is a key part of helping us collect safety data about the vaccine.

General risks

This study involves blood tests at all visits. Taking blood samples using a needle may sometimes result in bruising to the area, and some people can feel faint. If you do feel faint, our staff will ask you to stay at the clinic until you feel well again. It is also possible that blood tests taken during the study could show that you have anaemia (a low blood haemoglobin amount). If this happens, we will discuss this with you.

What if something unexpected is found?

As we carry out several medical tests during the study, it is possible that we discover previously unknown health issues (e.g. high blood pressure or abnormal blood results).

If abnormal results or previously undiagnosed conditions are found during the study, we will discuss these with you and, if you agreed, your GP would also be told about these results. Sometimes 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 must by law 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 must send a report to the UKHSA, including your personal contact information. It's important to understand that **you cannot opt out** of this as it is the law.

What are the benefits of taking part in the study?

There is **no direct benefit** to you from taking part in the study.

As part of the screening checks you will receive information about your general health, but this is not a health check.

You should not assume you will gain any protection from future Bundibugyo virus disease even if you receive the ChAdOx1 Ebola BDBV Vaccine (Recombinant) within the study.

What else do I need to consider?

Other vaccinations

If you need any vaccinations for health, travel, or work **during the study**, you should tell the study team before you have the vaccine.

Medications

If you begin taking any new medications, including antibiotics, during the study, please tell the study team. This includes medicines prescribed by a doctor or those you may buy yourself “over the counter” without a prescription.

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 can also change your mind and stop taking part in the study at any time, even after the study had begun. This will not result in any penalty or change to your medical care. If you do stop during the study, we will use the samples and data we have collected from you in our analysis of the study up until the point you told us that you wanted to stop, 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), the study team or the sponsor of the study may stop you taking part early, before the end of the study. If this happens, we may ask you to still attend safety follow-up visits with your consent.

Will I be paid for taking part?

You will not be paid for taking part in the study, but you will be reimbursed for your time, travel, and the inconvenience. The maximum reimbursement for any volunteer in **Cohort 1** who completes all visits is up to **£1200**. The maximum reimbursement for

any volunteer in **Cohort 2** who completes all visits is up to **£790**. All participants will be reimbursed based on the following amounts:

Study visit	Description	Amount
Screening	Screening	**£110**
Day 0	Vaccination visit	**£110**
	Full completion of each Ediary	**£30**
Day 7, 14, 28, 84, 180, 187, 194, 208, 264, 365	Follow-up visits (cohort-dependent)	**£90** per visit
Day 180	Vaccination visit (cohort 1 only)	**£110**
Unscheduled visit(s)	If required at the discretion of the study team	£90 per visit
Maximum* amount per participant in total **Cohort 1**		**£1200**
Maximum* amount per participant in total **Cohort 2**		**£790**

*(not including unscheduled visits)

Payments are made directly by bank transfer in instalments during the study. For this reason, we ask participants to provide their bank details (including account name, sort code and account number) at the screening visit. Payments cannot be made in any other way, including cheque or cash.

Personal information such as your name, bank details and national insurance number may be shared with the University of Oxford finance team to process or verify your payments. Financial auditors may also audit the records where this information is held. Your bank details will be stored securely for 7 years in accordance with University of

Oxford Financial policy. All confidential data will be stored according to the UK General Data Protection Regulation.

You may also receive reimbursement for any **unscheduled** (extra) visits you are asked to attend by the study team. You would be reimbursed £90 per unscheduled visit.

The amount of money reimbursed is only for the parts of the study that you complete. If for example you choose to withdraw halfway through the study, or do not complete all study procedures, we would work out your reimbursement based on the visits that you did attend and samples that have been taken from you. The reimbursement will be provided at different times during the study.

Bank details are kept confidential. More information about how we handle your financial data can be found at section below 'What happens to my data?'.

We will not pay tax or National Insurance from the money due to you. It is your responsibility to pay these and to check how any compensation received from taking part in the study affects any state benefits to which you are entitled. Contact HM Revenue & Customs for information (www.hmrc.gov.uk or telephone 0300 200 3300).

Contact HM Revenue & Customs for more information:

www.hmrc.gov.uk or call **0300 200 3300**

Why have I been invited?

You have been invited because you may be **suitable to take part** in this study and you may have also seen an advert or registered your interest in taking part in research.

For more information about how we approach and invite individuals to take part in our research please visit our website:

https://www.ovg.ox.ac.uk/research/recruitment

What will happen to the samples I give?

- Most study samples will be analysed in **University of Oxford** and **NHS** laboratories.

- Samples may also be sent to other **academic** or **commercial** research partners in and **outside the UK** to support sample analysis.
- Samples taken will be used to monitor safety and look at your **immune responses** to the ChAdOx1 Ebola BDBV Vaccine (Recombinant).
- How different individuals' respond to vaccines depends on their genetics, in particular genes called Human Leukocyte Antigen (HLA) genes. We will test the type of HLA genes you have in this study.
- Some blood samples will be used to look at the **pattern of genes** being actively used by your body in response to the vaccine. Your body's response to infection is in part controlled genetically, so knowing the pattern of genes that are being used may help us to understand how individuals respond to vaccines. Unfortunately, we will not be able to share the results of these genetic tests with you.
- **Clinical safety blood samples** are sent to local NHS laboratories and follow local sample labelling requirements (which will 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**.
- Samples sent to research laboratories for processing, including outside of the UK will **not** have direct **personal identifiers** (they will be identified by a 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 if you agree for any remaining samples to be stored and **used in future research**. You will not be asked to donate any extra samples or undergo any extra procedures. You do not have to say yes to future research use to take part in this study. All samples will be stored with a code, instead of information that would identify you directly. If you do not agree to the storage for future research, any remaining samples will be thrown away at the end of 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 hospital records for this research project. We will share your information related to this research project with the following types of organisations
United Kingdom Health Security Agency (UKHSA) (please see page 23). This information **will include your name, NHS number, date of birth, contact information**.

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 and for arranging couriers to collect samples. This information will be **limited to what is necessary for the purpose**.

Other researchers and collaborators including the study funder, for the purpose of analysis of research samples. **Only de-identified data will be shared** with these.

We may use third party service providers or subcontractors to help with some of the research activities we carry out (e.g. IT provision, survey provision, transcription services, monitoring etc.). We may therefore share your personal data with these providers when it is necessary to do so to allow them to carry out the services, we require them to provide. However, we require all our third-party providers to have appropriate security measures in place to protect your data and we only allow them to process your data for the specific purposes we have stated in our instructions.

This information **will** include your National Insurance Number (UK citizens) or your passport number (non-UK citizens) initials, NHS number, name, date of birth **and** home address/contact details, including either **home address** or **phone number** or an **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. Responsible members of the University of Oxford, regulatory authorities and the relevant NHS Trust(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

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 the following methods:

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

- The University of Oxford Data Management and IT Team will be able to view your email address, which is necessary for the e-diaries to function.
- Any data held by the University of Oxford will be stored on secure servers Page 27
- Paper-based data will be stored in locked cabinets/storage with access restricted to authorised personnel

International Transfers

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

- **The study funder and approved academic or commercial research partners**,

We will make sure your data are protected. Anyone who accesses your data outside the UK must do what we tell them so that your data have a similar level of protection as it does under UK law. We will make sure your data are 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 see: 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 must. For further details about UK breach reporting rules 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.

After the study ends, the retention period (this means the length of time we keep your data for) will begin and we will keep your study data for a minimum of period of 25 years, in line with Clinical Trials Regulations. Once the retention period has finished, the study data will be kept in a way that does not identify you.

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 will ask if you are happy for us to continue collecting information about your health from central NHS records / your hospital / your GP for safety reasons. If you do not want this to happen, tell us and we will stop.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this 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** info@ovg.ox.ac.uk
- sending an email to the research team 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: 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:

www.hra.nhs.uk/patientdataandresearch

Further information about your rights with respect to your personal data is available on the University of Oxford website at:

compliance.web.ox.ac.uk/individual-rights

Additional Information

The study is **sponsored** and organised by the University of Oxford.

The study is **funded** by the **Coalition for Epidemic Preparedness Innovations (CEPI)**

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: Your information will be kept confidential and managed in accordance with applicable policies and regulations. We will ask for your consent to access your medical records to check your health before enrolling you in the study. We will inform your GP that you are enrolled in the study and provide information so that your medical records can be updated.

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). The data entered can be viewed by other users in TOPS for 2 years.

Patient and Public Involvement: Members of the Oxford Vaccine Group Patient and Public Involvement Group (PPI) were involved in the developing of the participant materials and will continue to be involved in the study.

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 will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research 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 doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary.

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 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: 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 [name of investigator] [contact details: phone number & email)] or you may contact University of Oxford Research Governance, Ethics & Assurance (RGEA) at rgea.complaints@admin.ox.ac.uk

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 **by email** and access to the full publication. Information will also be **available on the OVG website** 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.** 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 an MD or PhD.

Review: All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by London-Brent Research Ethics Committee. The Oxford Vaccine Group PPI group have reviewed the main participant-facing documents associated with this study (Participant Information Sheet and advertising materials).

Future research studies: If you choose to take part in this study, you will be asked if you agree to be contacted about other ethically approved research studies in the future, for which you may be suitable.

All contact will come from the Oxford Vaccine Group research team of this study in the first instance

Agreeing to be contacted does not oblige you to take part in future research.

You can be removed from this register at any time you wish.

If you would like further information about participating in research, please visit the following NHS website:

www.nhs.uk/tests-and-treatments/clinical-trials

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

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

ovg.ox.ac.uk/studies/ebola

If you have further questions about the study, please contact us at:
Email: info@ovg.ox.ac.uk
Tel: 01865 611400