Participant Information Sheet

Study Title: A clinical trial to assess three self-amplifying ribonucleic acid (saRNA) vaccines against Ebola, Marburg, and Lassa viruses (EML-Vac)

Study ID: EML-Vac **IRAS ID: 1012266**

Contents:

Invitation:

- We are looking to develop three new vaccines (EML-Vac) to prevent outbreaks of three viruses (Ebola, Lassa and Marburg) that are the major causes of viral bleeding fevers
- We invite you to participate in this first-in-human clinical trial to assess their safety and their ability to induce immune responses that may provide protection from infection or disease
- Before you decide to take part, it is important for you to understand why the study is being done and what it involves
- Please take time to read the following information carefully
- You are free to decide if you want to take part. Just ask us if there is anything that is not clear or if you would like more information
- Thank you for reading this

Brief Summary:

- We are testing three different vaccines alone and in combination against Ebola, Marburg and Lassa fever viruses
- You will get three injections that may include one, two, or all three vaccines, along with one, two, or no injections of a saltwater solution (placebo). You won't be told what you received until the study is over, so the results stay fair and unbiased.
- We don't know yet whether they will work, or what their side effects will be; we'll monitor your health very closely and you will be asked to remain in the clinic for an hour after each injection.
- You will be in the study for about 12 months, making 13 scheduled visits to the research site at Chelsea and Westminster Hospital in London
- Visits will last between 30 minutes and 3 hours
- There will be 2 visits when you will receive the three injections into the deltoid muscle of your arm(s). You may choose which arm to receive these injections.
- You will be paid for your time, travel and inconvenience: £200 per completed visit, plus an additional £200 upon completion of the final all visits. This will come to a total of £2800, inclusive of travel expenses.
- If you attend a screening visit, but are not selected to join the trial, we will reimburse £40 for attending your first pre-screening appointment, which includes a blood sample and other assessments.

Lead Researcher Contact:

If you have any questions about this study, please talk to the lead researcher:

Dr Marta Boffito

Tel 020 3315 6148

Email: marta.boffito@nhs.net

1. What is the Purpose of the Study?

EML-Vac is a study that is looking to develop trivalent RNA vaccines (Vac) against the Ebola, Marburg, and Lassa (EML) viruses. These viruses are the major causes of viral bleeding (haemorrhagic) fever, most often in parts of Africa.

The aim of the study is to assess the safety of these vaccines alone and in combination, since this will be the first time that these have been used in humans. But this trial is not looking at whether these vaccines are effective in terms of protection. It is just assessing their safety and how well the immune system responds to the vaccine.

Since this is the first time these vaccines have been used in humans, the safety will be assessed in healthy young adults. 40 participants aged 18-50 years will be randomised to one of five different groups receiving either Ebola, Marburg or Lassa virus self-amplifying RNA (saRNA) vaccines individually and two injections of saltwater solution (placebo), Ebola and Marburg virus vaccines and one injection

of saltwater solution or Ebola, Marburg and Lassa virus vaccines and no doses of saltwater. You won't be told what you received until the study is over, so the results stay fair and unbiased. You will receive two injections 12 week apart and be careful monitoring for any reactions to the vaccine. After vaccination, we will collect blood samples to assess your immune response to the vaccine.

2. Why have I been chosen?

You have been chosen based on meeting the criteria for the study detailed below. We will be enrolling a total of forty participants. You can take part only if you give your consent after being fully informed about what participation involves. A study doctor/nurse will discuss this written information with you.

There are strict eligibility criteria for participation:

- Healthy male and female volunteers aged between 18 and 50 years.
- Available for ALL follow-up visits for the duration of the study.
- Entered and clearance obtained from The Over volunteering Prevention System (TOPS) database (to avoid impact of any co-administered investigational products or treatments on our outcomes).
- Willing to avoid all other vaccines from within 4 weeks before the first injection through to 4 weeks after the second injection
- Women capable of becoming pregnant willing to use a highly effective form of contraception from enrolment through to at least 18 weeks after the second injection
- Willing and able to give written informed consent.
- Willing to abstain from donating blood for three months after the end of their participation in the trial or longer, if necessary

You will not be able to take part if you

- History of any medical, psychological or other condition, clinically significant laboratory result at screening, or use of any medications which, in the opinion of the investigators, would interfere with the study objectives or volunteer's safety.
- History of anaphylaxis (severe allergic reaction) or angioedema (sever swelling).
- History of a severe allergic reaction after receiving a previous dose of any COVID-19 mRNA vaccine.
- History of severe or multiple allergies to drugs or pharmaceutical agents
- Any history of myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart).
- History of severe local or general reaction to any vaccination defined as:
- local: extensive, indurated (thickened) redness and swelling involving most of the arm, not resolving within 72 hours.
- General: fever, >39.5°C within 48 hours; bronchospasm; laryngeal oedema; collapse; convulsions or encephalopathy within 72 hours.

- Immunocompromised or on a medicine that affects the immune system.
- Are HIV or HCV positive.
- Are pregnant or plan to become pregnant.
- Are breastfeeding.
- Unable to read and/or speak English to a fluency level adequate for the full comprehension of study procedures and consent.

There may be other reasons why you cannot take part – if so, the study doctor/nurse will discuss these with you.

At the end of the consenting process, which usually takes about 1 hour, the study doctor/nurse will ask you to sign a consent form.

3. Do I have to take part?

No. It is up to you to decide whether to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. Participation is voluntary and you are free to withdraw at any time without giving any reason (although we will usually ask you why), without your medical care or legal rights being affected.

4. What will happen to me if I take part?

All 13 visits will take place at the Clinical Research Facility at Chelsea and Westminster Hospital, 369 Fulham Rd, London, SW10 9NH. We will register you as a patient of Chelsea and Westminster Hospital NHS Foundation Trust before being consented to participate in the study.

Screening visit

After you have given your consent, we will screen you to ensure that you satisfy all the study's eligibility criteria. Screening will take about two hours, and includes:

- A discussion about medical history, including medication
- A symptom-directed physical examination
- Height, weight, blood pressure, heart rate, ECG, and oral temperature measurements
- Blood samples to check your health, and urine samples for pregnancy (women only).
- If any of your blood tests or other health checks come back as abnormal, these results will be passed onto your local GP.
- If you test positive for a notifiable disease (e.g., hepatitis or HIV, etc) during the screening procedures, you will be referred promptly to the correct clinic within the Hospital to ensure appropriate clinical management. The clinic will also notify the UK Health Security Agency, if required.

Injection visits

Injection visits will last about 3 hours. Before you are injected, we will do a basic health check (symptoms, medication, symptom-directed physical exam [if required], blood pressure, heart rate, ECG, and oral temperature), do a urine pregnancy test (women only) and collect blood samples.

You will be randomly assigned to one of five groups and you will get three injections in your arm (you can choose which arm) that may include one, two, or all three active vaccines, along with one, two, or no injections of a saltwater solution (placebo) (see table below). You won't be told what you receive until the study is over, so the results stay fair and unbiased.

Groups	Vaccines	Injections	Key
Group 1:	Active injection x 1 = LNP-MARVsaRNA-01 Placebo injection x2 = Saline		Active Vaccine = 
Group 2:	Active injection x 1 = LNP-EBOVsaRNA-01 Placebo injection x2 = Saline		Placebo Vaccine = 
Group 3:	Active injection x 1 = LNP-LASSAsaRNA-01 Placebo injection x2 = Saline		
Group 4:	Active injection x 1 = LNP-MARVsaRNA-01 Active injection x 1 = LNP-EBOVsaRNA-01 Placebo injection x1 = Saline		
Group 5:	Active injection x 1 = LNP-MARVsaRNA-01 Active injection x 1 = LNP-EBOVsaRNA-01 Active injection x 1 = LNP-LASSAsaRNA-01		

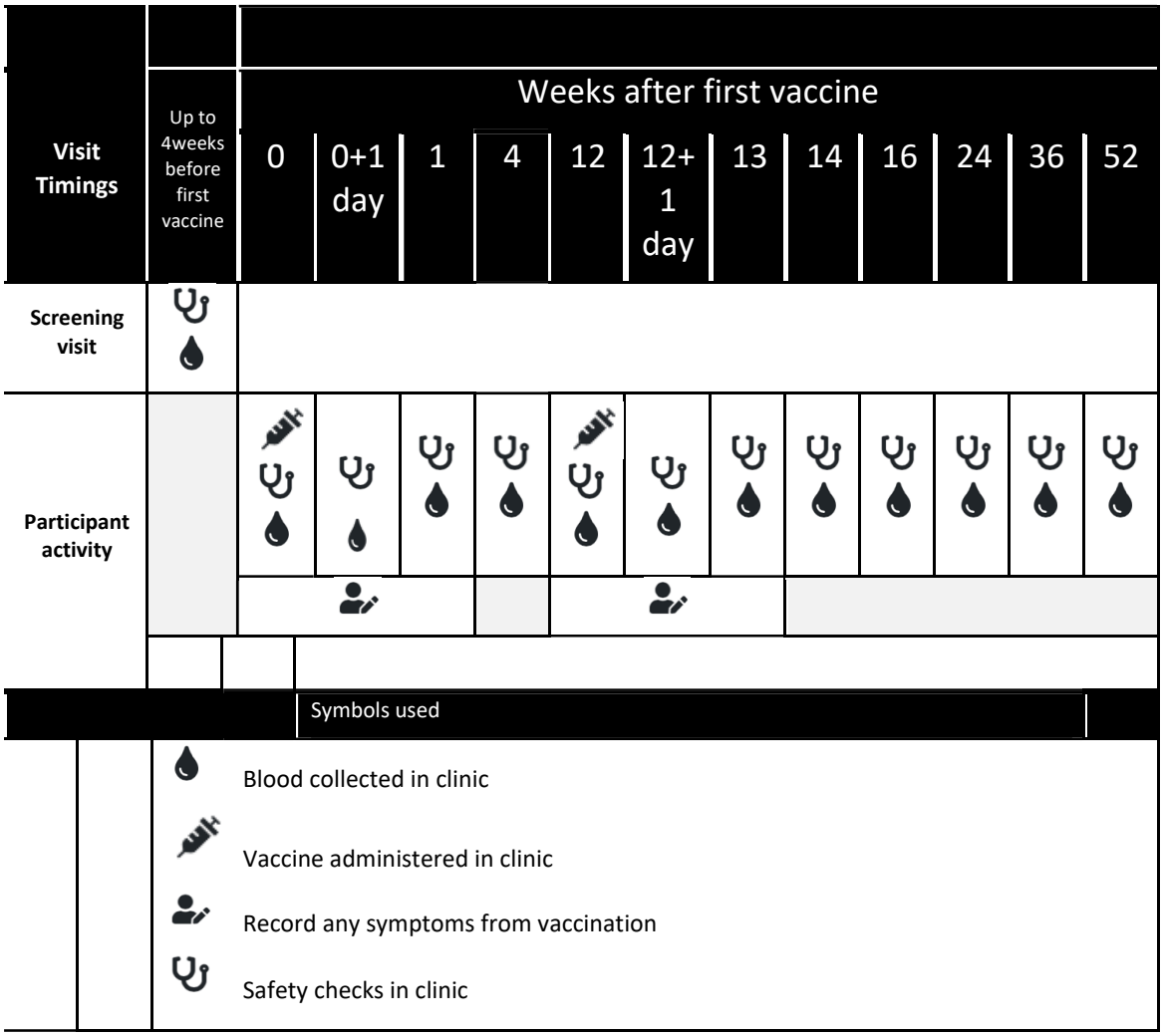
The **second, injection visit will be 12 weeks after the first injection**. It will be the same as the first injection visit.

After each injection, you will remain in the clinic for at least one hour so that we can monitor your health.

Follow-up visits and blood sampling

You will be required to attend the hospital for blood tests one day, one week and four weeks after your first injection and one day, one, two, four, twelve, twenty-four and forty weeks after the second injection. These visits will last about 1h. Visits must take place on the indicated days.

The visit schedule is summarised in the table below.



Total blood draw

We expect to take a maximum of 403 millilitres (just over half a pint) of blood over the course of the whole study.

Completion of diary cards

We'll also ask you to complete a symptom diary during the first 7 days after each vaccination

5. What do I have to do?

Every visit is very important to the study, so please agree to take part only if you genuinely expect to be able to attend them all.

You will need avoid all other vaccines from within 4 weeks before the first injection through to 4 weeks after the second injection, also to avoid giving blood during the study and through to 4 weeks after your last visit.

These vaccines have not been tested for safety in pregnancy. Women who could become pregnant must use a highly effective form of contraceptive during this study. The types of suitable effective contraception will be discussed with by your research doctor or nurse. Male participants with partners that are pregnant or could become pregnant should use male contraception (condom) during this study.

If you become pregnant while taking part in the study you must immediately tell the study team.

6. What is being tested

The vaccines currently being tested use specially made pieces of RNA that contain instructions for making important proteins from the Ebola, Marburg, and Lassa viruses. These proteins help the body produce protective antibodies against these viruses. Because the vaccines only use these proteins and not the whole virus, there is no risk of getting infected with the viruses directly from the vaccines.

Once injected into the muscle, these RNA vaccines can copy themselves, which means we can use smaller doses than usual. However, this self-copying process doesn't last long—only a few hours to days—after which the RNA breaks down naturally. Importantly, these vaccines cannot change your DNA or make any genetic changes.

Although there haven't been specific studies on these three vaccines yet, a previous study (COVAC-1) tested a similar RNA vaccine for COVID-19 in over 200 people. The results showed that it was safe and well-tolerated, with most side effects being mild or moderate.

7. What are the possible side-effects, disadvantages and risks of taking part?

Side effects from this vaccine are expected to be very similar to those seen with COVID-19 RNA vaccines including our own previous studies. Common, mild side effects (affecting more than 1 in 10 people) may include pain, tenderness, redness, warmth, itching, or swelling at the injection site. These usually go away within 1 to 7 days. You may also experience general side effects like fever, chills, muscle aches, tiredness, headaches, nausea, vomiting, or dizziness, which are also expected to clear up within a few days.

Less common side effects (affecting about 1 in 100 people) might include stomach pain, diarrhoea, sore throat, swollen lymph nodes, trouble sleeping, or mild allergic reactions like a rash or itching, but these usually resolve within a week as well.

Serious side effects are very rare. For example, mild allergic reactions like hives or swelling of the face may occur in about 1 in 1,000 people, while severe allergic reactions are extremely rare (about 1 in a million). People with a history of severe allergies will not be able to participate in the study. There have also been very rare cases of heart inflammation (myocarditis or pericarditis), especially in adolescent males, but this is still uncommon (1 in 37,000). If you have had either of these conditions before, you will not be eligible for the study.

Some people might faint during or after the injection or when having blood taken, especially if they have a fear of needles. We will take precautions by asking you to lie down during these procedures.

Blood draws may cause minor discomfort, such as pain or bruising, and in rare cases, a blocked vein or slight nerve injury, which may cause temporary numbness. These issues usually go away with time.

The vaccine hasn't been tested for safety during pregnancy, so if you're pregnant or planning to become pregnant, you can't participate in the study. You must also avoid becoming pregnant for four months after your last injection. If you do become pregnant, please let the study team know immediately.

8. What are the possible benefits?

Participating in this study won't provide any direct health benefits for you, but the information we gather could help in the development of vaccines to protect against Ebola, Marburg and Lassa viruses, responsible for sporadic outbreaks of viral bleeding (haemorrhagic) fevers, most often in parts of Africa.

We will compensate you for your time, inconvenience, and travel expenses. You'll receive £200 for each completed visit, At the end of your participation, you'll get a lump sum payment for all completed visits. If you attend all visits on time and follow the study requirements, you'll receive an additional £200. The maximum payment will be £2800, which is inclusive of all travel expenses. If the Principal Investigator withdraws you from the study for medical reasons, you will still receive full payment.

If you attend a screening visit, but are not selected to join the trial, we will reimburse £40 for attending your first pre-screening appointment, which includes a blood sample and other assessments.

9. Supporting information

What will happen if new information becomes available?

Sometimes during a research project, new information becomes available about the agent that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to continue in the study, you will be asked to sign an updated consent form.

Also, on receiving new information, your research doctor might consider it to be in your best interests to withdraw you from the study. Your doctor will explain the reasons and arrange for your care to continue.

What happens if the study stops early?

If the study is stopped early, you will be paid for the number of scheduled visits you've completed, and the reasons for stopping the study will be fully explained to you.

What if something goes wrong?

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury because of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College London is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during this study, then you should immediately inform the Investigator (Dr **Marta Boffito:** Tel 020 3315 6148; Email: marta.boffito@nhs.net). The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team (RGIT@imperial.ac.uk).

What if I have a complaint?

If you wish to complain, or have any concerns about any aspect of the way you have been treated, please contact:

- Dr **Marta Boffito:** Tel 020 3315 6148

If you'd prefer to speak to someone independent of the study, the normal NHS complaint mechanisms are also available to you:

- Patient Advice and Liaison Service (PALS): Tel 020 3315 6727 (Mon–Fri 9am–5pm), or email

chelwest.cwpals@nhs.net

What will happen to the results of this study?

We hope to publish the results in open-access peer-reviewed medical journals and present them to the wider scientific community at international conferences. You will not be named in any of these or identified in any other way. The results and description of the study will also be available on the public website www.clinicaltrials.gov.

Will my taking part in this study be kept confidential

Yes. In this research study we will use information from you. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. These will include Imperial research Team members and support staff.

Everyone involved in this study will keep the data collated as part of this study, including your personal data, safe and secure. We will also follow all privacy laws and legislation that are relevant to the specifics of the study.

At the end of the study we will save some of the data in case we need to check it and for future research.

We will make sure no-one can work out who you are from the reports we write.

If it arises that a volunteer who has given informed consent, loses capacity to consent during the study, the participant and all identifiable data or tissue collected will be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.

A description of the study will also be available on the public website clinicaltrials.gov. This website will not include information that will identify you. You will be able to access a summary of the results via the website when the study has been completed. You can ask a member of staff for more details about which website the information is available on.

Your details will be entered on The Over-volunteering Prevention System (TOPS), which aims to prevent volunteers from taking part too frequently in clinical research studies. This is not a public database and can only be accessed by various registered clinical sites.

How will we use information about you?

Imperial College London is the sponsor for this study and will act as the Data Controller for this study. Being a Data Controller means that we are responsible for looking after your information and using it appropriately plus are responsible for explaining this to you. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

The study data will then be fully anonymised and securely archived or destroyed.

The study is expected to finish in November 2026

For more information / confirmation regarding the end date please contact the study team, see **'WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED'** for contact information.

We will need to use information from you and your medical records for this research project.

This information will include your NHS number, name, date of birth and contact details.

People within the University/Trust and study team (see section sharing your information with others) will use this information to do the research or to check your records to make sure that research is being done properly and the information held (such as contact details) is accurate.

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.

Imperial College London is the sponsor of this research, and is responsible for looking after your information. We will keep all information about you safe and secure by:

- Data management plans have been created and reviewed in line with Imperial's Information Governance Policy Framework. This covers the collection, movement, processing and storage of the data.
- Data to be stored in a dedicated secure environment which underpins security measures.
- Robust pseudonymisation has been implemented to prevent identification
- Access controls have been implemented to ensure only key personnel can access the data.
- Some of your information may be sent to other countries. They must follow our rules about keeping your information safe.

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.

As a university we use personally-identifiable information to conduct research to improve health care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

• Imperial College London - "performance of a task carried out in the public interest"; Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research

Where special category personal information is involved (most commonly health data, biometric data i.e. finger prints or facial recognition and genetic data, racial and ethnic data etc.), Imperial College London relies on "scientific or historical research purposes or statistical purposes .

International Transfers

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

- Where necessary to provide access to a service provider who will utilise your personal data as instructed by us.

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 other researchers

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:

- we use specific contracts which stipulates that personal data must maintain the same level of protection when outside the UK as it has within the UK. For further details visit the Information Commissioner's Office (ICO) website - www.ico.org.uk
- 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

Sharing your information with others

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

- Other Imperial College London/Chelsea and Westminster Hospital NHS Foundation Trust employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London/Chelsea and Westminster Hospital NHS Foundation Trust agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

Potential use of study data for future research

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about 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 access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. 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 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.

Where can you find out more about how your information is used?

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.

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to **dpo@imperial.ac.uk**
- by ringing us on **020 7594 3502**.

Contact Us

If you wish to raise a complaint on how we have handled your personal data or if you want to find out more about how we use your information, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

The Clinical Research Facility (CRF) will collect information from you for this research study in accordance with our instructions. The CRF 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, and to oversee the quality of the study. Individuals from Imperial College London and regulatory organisations may look at your research records to check the accuracy of the research study. The CRF will pass these details to Imperial College London along with the information collected from you. The only people in Imperial College London who will have access to information that identifies you will be people who need to contact you to discuss your results or the study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details. The CRF will keep identifiable information about you from this study for 10 years after the study has finished.

What will happen to any samples I give?

As part of the study, some samples will be tested at the host NHS site, and some at Imperial College London. Other samples might be sent from Imperial College London to other labs both inside and outside of the UK. These labs won't have access to your personal identifiable information. Once the study is complete, we will keep your samples for up to 10 years in case we need to repeat any experiments. In addition, we might use some of your samples to help us with other vaccine research.

However, if you do not want us to use your samples in other research, you can opt out of this in the consent section below and this will not affect your eligibility to participant in this current trial.

Who is organising and funding the study?

The study is organised by Imperial College London, UK. The study is funded by a grant from Innovate UK, part of UKRI with additional funding provided by a philanthropic donation from Partners of Citadel and Citadel Securities. The investigators do not receive any payment for this study. The host NHS site is the Chelsea and Westminster Hospital NHS Foundation Trust.

Who has reviewed the study?

This study has been reviewed and approved by the XXX Research Ethics Committee, the Health Research Authority, and by the Research & Development office of the host NHS site.

Contacts during the study, including emergencies

You can contact the study nurses and doctors on Tel 0203 315 5601 (Mon–Fri 9am–5pm).

For **emergencies** outside those hours, please call 07825 681110 and tell the person who answers that you are a volunteer in the EML-Vac study at the CRF, and the nature of the emergency; a call-back will be arranged. Alternatively, please dial 111, visit your GP or the nearest NHS Drop-In or Accident and Emergency Department if you have any medical concerns.

Thank you for your interest in taking part in this study. If you choose to proceed to the screening assessments, you will be given a copy of this information sheet and your signed consent form to keep.

10. Consent Form **Subject ID: _____**

Study Title: A clinical trial to assess three self-amplifying ribonucleic acid (saRNA) vaccines against Ebola, Marburg, and Lassa fever viruses (EML-Vac)

Study ID: EML-Vac **IRAS ID: 1012266** **CI: Marta Boffito**

Write initials in box to confirm your consent to each statement below:

I confirm that I have read the participant information sheet version 2.0_05SEP2025 for the EML-VAC study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	* ☐
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	* ☐
I understand that my relevant medical history, and data collected during the study, may be looked at by individuals from Imperial College London or from the host NHS Trust, where it is relevant to my taking part in this study. I give permission for these individuals to have access to my records.	* ☐
I give permission for my samples and data to be analysed, at various sites within and outside the UK, and the results published in a way that doesn't identify me.	* ☐
I understand that blood samples and / or data collected from me are a gift donated to Imperial College and that I will not personally benefit financially if this research leads to an invention and/or the successful development of a new test, medication treatment, product or service.	* ☐
I agree to my General Practitioner being informed of my participation in the study	* ☐
I agree to being entered onto The Over-Volunteering Prevention System (TOPS).	* ☐
I give permission to be contacted by the trial team via email or telephone to be informed of the results of the EML-Vac trial	* ☐
I give permission for my samples to be stored and used for ethically approved studies after the end of this study (this is a voluntary consent. If you do not wish for your samples to be used after the end of this study, please select "N". This will not affect your eligibility to participate in EML-Vac).	* ☐

I agree to take part in the above study.

Name of participant	Date	Signature
Name of person taking consent	Date	Signature

When completed: 1 copy for participant; 1 copy for investigator site file; 1 copy to be kept in medical notes.