PARTICIPANT INFORMATION SHEET AND CONSENT FORM- UNITED KINGDOM

SPONSOR / STUDY TITLE:	ModernaTX, Inc. / A Phase 3, Randomized, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1647 Cytomegalovirus (CMV) Vaccine in Healthy Participants 16 to 40 Years of Age
SHORT STUDY TITLE:	mRNA-1647 vaccine for Cytomegalovirus (CMV)
PROTOCOL NUMBER:	mRNA-1647-P301
PRINCIPAL INVESTIGATOR (STUDY DOCTOR):	Dr Simon Drysdale St George's University Hospitals NHS Foundation Trust Blackshaw Road London, SW17 0QT Tel: 02087255382 Email: modernacmv@sgul.ac.uk Out of Hours Tel: 07821810046 (24 hour emergency number)
ETHICS COMMITTEE:	London - South East Research Ethics Committee

Invitation

You are being invited to take part in a clinical research study, sponsored by ModernaTX, Inc. (Moderna). Please read this informed consent form carefully and ask the study staff to explain words or information that you do not clearly understand. Please feel free to talk to others about the study if you wish. It is important that you know the following:

- Your participation is voluntary.
- You may or may not benefit from participating in this study. However, your participation may help others in the future as a result of knowledge gained from this study.
- You may choose to leave the study at any time.
- If you choose not to take part or if you leave the study, it will not harm your relationship with your study doctor or the hospital.

This informed consent form describes what you will be asked to do before, during, and after the study. It also describes the risks and possible benefits of the study. If you decide to take part in this study after reading this form, you will be asked to sign and

date this consent form before any study procedures are performed. Signing and dating this consent form indicates that you understand your involvement in the study and the risks of participating in the study and that you agree to take part in the study. A copy of this signed and dated form will be given to you to keep.

Your study doctor and the staff at the study site, Moderna and its representatives will closely evaluate your safety and the safety of others participating in this study.

INFORMATION ABOUT THIS STUDY

Why have I been invited?

You are being invited to take part in this research study to test a study vaccine called mRNA-1647 that is being developed for preventing cytomegalovirus (CMV) infection in people. You have been invited to take part in this study because you are aged between 16 and 40 and potentially have contact with young children.

CMV is a common virus that can spread through an infected person's saliva or other body fluids such as blood, urine and breast milk. It is unusual for a CMV infection in a healthy person to cause illness, but when it does, symptoms may include fever, muscles aches all over the body, moderate to severe fatigue, sore throat/swelling at back of throat, and/or swollen neck glands.

However, if a pregnant woman has a CMV infection, it may be passed to her unborn child, causing the baby to be born with CMV infection - this is called "congenital CMV infection". CMV is the most common infectious cause of congenital birth defects (present at or before birth). Although most infants who are born with congenital CMV are well, some infants with congenital CMV infection can have severe symptoms and have or develop lifelong disabilities such as hearing loss, learning problems, or vision abnormalities and rarely it can cause death.

The most common source of CMV infection in pregnant women is young children. Young children commonly catch CMV and can shed the virus in their saliva and urine for long periods of time. So, women who are in regular contact with young children are at the highest risk of catching CMV during pregnancy.

The use of a safe and effective vaccine may potentially prevent CMV infection. There is currently no approved vaccine to prevent CMV infection.

For more information on CMV please visit the weblink below:
https://www.nhs.uk/conditions/cytomegalovirus-cmv/

What is the Purpose of this clinical research study?

The main goals of this study are as follows:

- To understand if mRNA-1647 can prevent CMV infection in participants who have not been previously infected with CMV. A blood test to confirm if you have had CMV infection in the past will be performed as part of the assessment in this study.

- To understand the safety of mRNA-1647 study vaccine

How many people will participate in this study?

About 6,900 healthy participants (16-40 years of age) will take part in this study. This study will be conducted at approximately 150 study sites in various countries.

Do I have to take part?

No. It is up to you to decide. Your participation in this study is voluntary and you may refuse to participate or withdraw from the trial at any time without penalty or loss of benefits to which you are otherwise entitled. If you do decide to participate you will need to read this information sheet and sign a consent form to show you have agreed to take part.

What is the study vaccine that is being tested?

The study vaccine mRNA-1647 is an investigational vaccine. An investigational vaccine is not approved by any regulatory agency, such as the Medicines and Healthcare products Regulatory Agency (MHRA). It can only be used in a research study like this one. So far, Moderna has 2 ongoing research studies with mRNA-1647.

Vaccines prepare your immune system for fighting infection and preventing illnesses.

The mRNA-1647 vaccine is a messenger RNA (mRNA) vaccine. The mRNA is entirely made in a laboratory and instructs your body to make proteins similar to the ones found in CMV. The immune system recognises this protein and causes your body to make antibodies (protective proteins) to fight the virus if it enters the human body in the future. The mRNA-1647 vaccine is not made from the CMV and cannot cause infection. The mRNA-1647 vaccine breaks down naturally and does not stay in the body. In this study, mRNA-1647 will be compared with a placebo. The comparison with the placebo helps to show any potential side effects of mRNA-1647. The placebo will be a salt-water solution that does not have any vaccine product in it.

What will happen during the study?

You will be in the study for approximately 30 months (2.5 years), and you will have visits with the study team approximately 14 times. You may not have to return to the site for all 14 visits if you choose to have the visit conducted at your home. The study team will discuss these options with you. You will be contacted approximately 21 times for safety data collection either by telephone or through receipt of electronic diary (eDiary) safety survey messages.

This is a Phase 3 study in which you will be enrolled into 1 of 2 groups: seronegative group (5,500 female participants) or seropositive group (1,400 female participants). Seronegative group refers to participants who test negative for CMV infection when they first enter the study. The seropositive group refers to participants who had CMV infection in the past. You will have a blood test at the initial study screening visit to confirm if you have had a CMV infection in the past. You will be informed whether you are CMV-seronegative or CMV-seropositive from the initial screening test.

Within each group, you will be assigned by chance (like flipping of a coin) to receive mRNA-1647 or placebo. A computer decides whether you will receive mRNA-1647 or placebo. The chance that you will receive either mRNA-1647 or placebo is 50%. You will not be able to choose the group to which you will be assigned. The study is observer blinded, which means that neither you nor the study doctor will know whether you receive mRNA-1647 or placebo. However, the study doctor will be able to find out if needed in an emergency.

If you participate in this study, you will receive a total of 3 separate injections of either mRNA-1647 or placebo into the muscle in your upper arm over a period of 6 months. All 3 injections will be either mRNA-1647 or placebo depending on whether you are assigned to mRNA-1647 or placebo at the start of the study. After each injection, you will remain at the study site for an observation period of approximately 30 minutes so that the study doctor or a member of the study team can observe whether you have any immediate allergic reactions to the study vaccine.

From this point on, any references to the word “study vaccine” can mean mRNA-1647 or placebo.

What procedures are involved

Screening Visit: If you want to be in this study, you will be asked to provide informed consent. Your study doctor will check whether you are eligible to take part in this study and whether this study is right for you. You will also have to undergo a blood test to confirm if you have had a prior CMV infection. Screening must be completed in no more than 28 days before you get the first dose of study vaccine.

Study Vaccination Phase (Day 1 to Month 7): If you are eligible and agree to participate in the study, you will need to come to the study site on Day 1 for your first injection of study vaccine. The second injection will be given approximately 2 months later around Day 57, and the third injection approximately 4 months later around Day 169 (during Month 6). This phase of the study will last for 7 months.

Follow-up Phase (Month 8 to Month 30): Safety follow-up and follow-up study assessments will be done from 8 months through approximately 30 months after you have received the first study vaccine injection.

If you or your study doctor decide to stop study vaccination after receiving the first study vaccination, you may still continue in the study for follow-up procedures. If you decide to leave the study early for any reason, you will be asked to be followed for your safety.

All Participants:

The list below shows some of the key procedures and assessments that will be done during the study. There is a table later in this form to show what happens at each visit.

- **Medical history:** Review of your health history to make sure you can join the study.

- **Medications:** Review of all medications including prescription medications, recent vaccinations, over the counter medications, dietary supplements, vitamins, and herbal medications you are taking or have taken before you join the study and during the study.

- **Demographics:** You will be asked about your age, sex, race and ethnicity.

- **Physical examination:** A complete physical examination including height and weight will be performed at screening. A symptom-based physical examination will be performed at follow-up visits if needed. This includes examination of the arm in which you received the injection and associated lymph nodes.

- **Vital signs:** Your body temperature, heart rate, respiratory rate, and blood pressure will be measured. They will be measured before and after you receive the study vaccine. You will be provided with a thermometer to record your body temperature.

- **Urine pregnancy test:** A urine sample will be collected to perform a pregnancy test. A urine dipstick test will be used for the pregnancy test.

- **Breastfeeding status:** At study injection visits, you will be asked if you are currently breastfeeding.

- **Electronic Diary (eDiary)/safety follow-up eDiary/eDiary Questionnaires:** You will be asked to report on symptoms you might experience after receiving each study vaccination and certain information about your health using an eDiary. This eDiary is asecured application (or “app”) that will be downloaded onto your smartphone. If you do not have a smartphone, an eDiary device may be provided to you based on availability for use during the study. This eDiary device should be returned to the study staff when all study entries have been completed. You will be trained by the study staff on how to use the eDiary and will complete an entry at approximately 30 minutes after study vaccination at the clinic. You will continue to record data in the eDiary each day after leaving the study site, preferably in the evening and at the same time each day, on the day of dosing and 6 days after dosing. If a reported symptom continues beyond 7 days, you will receive prompts to continue reporting the symptom until it is no longer reported (not beyond 28 days). The eDiary data will be reviewed either by telephone or during in-person study visits. The data collected through the app will be kept safe and processed only by authorized study team.

To fill out the eDiary entry, you will be asked to:

- Look at your arm where you received the study vaccine and measure specific reactions you may see (you will be provided a ruler);
- Check for underarm swelling or tenderness on the same arm where you were vaccinated;
- Describe any reactions after study vaccination;
- Measure your temperature (an oral thermometer will be provided to you);
- Note if medications were taken;

- Describe any other types of reactions or illnesses that you may experience.

- You will receive Safety eDiary prompts (alert) starting at Month 8. This will alert you to report any changes in your health that may occur during the Follow-up Phase between study visits.

- **Questionnaires:** If you are in the seronegative group (which means without a prior positive CMV test result) and report any illness symptom(s) that may meet criteria for possible CMV infection at Month 3 or after this time during study visits or in your responses to the Safety eDiary prompts, you may be asked to complete two standard questionnaires via eDiary depending on the timing of illness symptoms and availability of the questionnaires. The questionnaires will assess your general health status and the impact on your daily activities (household activities, classes/homework, and employment). You may be asked to complete these questionnaires more than once.

- **Study Vaccination:** You will be given the study vaccine that was assigned to you by chance. After the study vaccination, you will be asked to stay at the study site for at least 30 minutes so that the study doctor or member of the study team can observe whether you have any immediate reactions to the study vaccine.

- **Health and medications:** Throughout the study you should inform the study doctor if you have any changes in your health, illnesses, have to visit a healthcare provider (for example an accident and emergency room visit, office visit in person or telemedicine visit through video), changes in any of your medications, start taking new medications, or have received any other vaccinations since you started in the study. Inform the study doctor immediately if you experience any reaction or a side effect after study vaccination.

Blood tests: A needle will be used to collect blood from a vein in your arm. The total volume of blood taken from you during the study will be no more than 500 mL or about 34 tablespoons over the course of 30 months in the study. This is approximately the volume that is taken during a typical blood bank donation. Sometimes a blood test may need to be repeated. This can be done at an unscheduled visit. Blood will be collected to see whether your body is producing antibodies to the study vaccine (known as immunogenicity). The volume of blood collected in seropositive participants will be 17ml on visit 1,4,8,13,19,25,31. The volume of blood collected for seronegative group will be 6ml on visit 3,7,11,16,22,28; and 23ml on visit 1,4,8,13,19,25,31.

Study Visits: The study visits consist of both in-person and telephone contacts. In-person visits will take place at the study site, or if permissible and available, the study staff may ask if they or a representative may come to your home in order to perform the scheduled assessments. If any in-person visits must be performed at your home, the site will notify you before the visit takes place. A home visit will only take place if verbally agreed upon and approved by you prior to the visit. Study vaccination will only take place at the study site.

In between the in-person visits, study staff will contact you via phone to ask you questions about any symptoms or changes in health you may have and if there have been any changes to your medicines or non-study vaccines.

In addition, there may be circumstances in which you are not able to visit the study site in person due to travel restrictions or other limitations as a result of the COVID-19 pandemic. If this occurs, the study staff may request to conduct the visit via telemedicine. Telemedicine visits are visits that happen using the camera on your phone or computer.

A detailed description of the procedures for each study visit and telephone call is presented in Appendix 1 of this document. In addition, depending on whether you are in the seronegative or seropositive group, you will have different samples collected for testing as follows:

Seronegative Group:

If you are in the seronegative group, at each in-person visit, a blood sample will also be collected to test if you have had a CMV infection since your last visit.

If one of your results comes back positive, you will be informed of this test result, and will be asked to come to the clinic for an unscheduled visit. This visit will include an exam and collection of blood, urine, and saliva for further testing related to CMV. After this visit, you will return to your usual visit schedule and will have urine samples collected at remaining study visits instead of blood samples for CMV infection.

Illness Assessment Visit (Seronegative Group):

If you are in the seronegative group, and report any illness symptom(s) that may meet criteria for possible CMV infection at Month 3 or after this time during study visits, safety telephone calls or in the safety eDiary, you may be assessed by the study site for an illness visit. Possible CMV infection symptoms may include any 2 of the following symptoms: fever (temperature greater than or equal to 38°C/100.4°F), muscles aches all over body, moderate to severe fatigue, sore throat/swelling at back of throat, and/or swollen glands inside of neck **without** any respiratory symptoms (such as nasal congestion, runny nose, cough).

The illness assessment visit will include:

- Physical examination
- Blood collection for general health
- Blood test to check for CMV infection, Epstein-Barr virus, a common virus that can cause symptoms similar to CMV and human immunodeficiency virus (HIV)
- Urine sample to check for presence of CMV
- A nasal swab for coronavirus disease 2019 (COVID-19) (based on study doctor decision).

- Questionnaires: You may receive additional eDiary questionnaires to assess your general health status and the impact of CMV infection on your daily activities (household activities, classes/homework, and employment). Depending on timing of illness symptoms and availability of the questionnaires.

You will be informed of the outcome of these blood and nose swab tests. If your test for CMV infection comes back positive, you will be asked to come to the clinic for an unscheduled visit. This visit will include an exam and collection of blood, urine, and saliva for further testing related to CMV. After this visit, you will return to your usual visit schedule and will have urine samples collected at remaining study visits instead of blood samples for CMV infection.

Seropositive Group:

If you are in the seropositive group, at each in-person visit your urine will be collected for testing related to CMV.

What is expected from you?

When deciding whether to participate, consider whether you are able and willing to do the following:

- Agree to attend study visits.

- Tell the study doctor about any new medications, vaccines or planned vaccines other than the study vaccine you take during the study.

- Tell the study doctor about any non-study vaccines you have received during the period starting 28 days before the first injection. You will be requested to avoid receiving any non-study vaccine within 28 days prior to and after any study injections. Exceptions include influenza (flu) vaccine, which should be avoided within 14 days before or after any study injection. Any Coronavirus disease 2019 (COVID-19) vaccination series must have been completed a minimum of 28 days prior to receiving any dose of the study injection. COVID-19 vaccines (regardless of manufacturer) should be avoided 28 days before or after any study injection.

- Tell the study doctor if you are currently breastfeeding at each study injection visit.

- Give correct and accurate information about your health history and current health.

- Tell the study doctor about any health problems that you have during the study.

- Enter all data in the eDiary for 7 days, including day of study vaccination, following each study vaccination as instructed.

- Practice adequate birth control or avoid activities that could result in pregnancy for at least 28 days before the first study injection, and through 3 months after the 3rd study injection (for 9 months after the first study injection).

Note: An adequate birth control method is defined as consistent and correct use of an approved contraceptive method in accordance with the product label. This includes the following:

Birth control methods that may be considered as highly effective
Methods that can achieve a failure rate of less than 1% per year when used consistently and correctly are considered as highly effective birth control methods. Such methods include:

- Combined hormonal contraception associated with prevention of normal menstruation
  - Oral,
  - Vaginal,
  - Dermal

- Single hormonal contraception associated with prevention of normal menstruation

  - Oral,
  - Injectable,
  - Implantable,
  - Uterine device,
  - Uterine hormone-releasing system,
  - Tubal blockage on both sides,
  - Partner who underwent vasectomy (partner who underwent vasectomy is a highly effective birth control method provided that partner is the sole sexual partner of the trial participant and that the partner was seen by medical provider for the success of vasectomy
  - Sexual abstinence (sexual abstinence is considered a highly effective method only if defined as refraining from heterosexual intercourse during the entire period of risk associated with the study treatments. The reliability of sexual abstinence needs to be evaluated in relation to the duration of the clinical trial and preferred and usual lifestyle of the subject.)

Acceptable birth control methods that may not be considered as highly effective
Acceptable birth control methods that result in a failure rate of more than 1% per year include:

- Single oral hormonal contraception which does not depend on prevention of normal menstruation
- Male or female condom with or without spermicide
- Cap, diaphragm, or sponge with spermicide

A combination of a male condom with either a cap, diaphragm, or sponge with spermicide (double barrier methods) are also considered acceptable, but not highly effective, birth control methods.

Birth control methods that are considered unacceptable
Periodic abstinence (calendar, based on body temperature, or signs and symptoms of fertility awareness during menstrual cycle), withdrawal, spermicides only, and

amenorrhea (absence of menstruation) due to breastfeeding are not acceptable methods of contraception. A female and male condom should not be used together.

- If you become pregnant, tell your study doctor as soon as you know (for additional information, please see section on “Are there any reproductive risks?” below).

- Agree to not post or discuss the study on social media.

- Be in touch with your study doctor or study staff and tell them if you have a change in your contact details or if you no longer wish to be in the study.

- Agree to not take part in any other interventional clinical study (for 28 days) before starting the study or during the study.

What will happen at the end of the study or if you stop your participation early?

The study doctor will contact you when the study is close to the end and ask you to return to the study site for your last study visit. At this visit, a final examination will be completed and collection of blood, urine and/or saliva samples may be done. Your study doctor will also tell you if additional follow-up is needed and if you need to visit the study site again. You will not be able to get study vaccine after the study is over. Your study doctor will discuss your future health care choices with you.

Your study doctor and/or Moderna may also learn new facts during the study that might make you want to stop receiving the study vaccine or leave the study. You will be told about the new facts in a timely manner. You can then decide whether you want to still be in the study. If you leave the study, there will be no penalty and you will not lose any benefits you are entitled to. Leaving the study will not affect the quality of the health care you are given.

The study doctor may stop study vaccine or end your taking part in this study for any of the following reasons, for example:

- Receiving study vaccine or staying in the study would be harmful for you.

- You need treatment that is not allowed in this study.

- You did not follow instructions about what to do in the study.

- The study is cancelled, or your study vaccine group is stopped, or study enrollment goal is met.

- You experience a serious reaction or intolerable side effect that is not related to study vaccine.

- You are not interested in continuing with the study.

- Moderna may stop the study at any time for any reason.

The study doctor will tell you the reason(s) why you should not receive further study vaccine and/or why you should stop being in the study. If you become pregnant during the study, you will not receive any additional study vaccinations, however, you will continue to be followed in the study. The study doctor will advise you about your health care and will ask about your pregnancy and its outcome (for additional information, please see section on “Are there any reproductive risks?” below).

If you leave the study early or if you stop taking the study vaccine early and decide to leave the study, the study doctor will ask you to complete the end of study tests (such as a final health examination and laboratory tests). If you cannot see the study doctor in person, someone from the study staff will call you by telephone. You will be contacted by study staff 3 times by telephone if you do not return for scheduled visits or follow-up.

This is done to have complete data about your health and safety at the end of the study.

What are the potential risks and discomforts?

If you choose to take part in this study, you are at risk for side effects listed in this section. You should discuss these with the study staff and, if you choose, with your regular doctor.

Participants in prior mRNA-1647 studies received between 1 and 3 doses of the study vaccine, including doses up to 300 micrograms, which is 3 times as much as the dose in this study. With any vaccination, you may experience side effects such as those listed below.

- Pain at the injection site
- Redness and swelling/hardness of the skin at the injection site
- Under arm swelling on the side of study vaccination
- Headache
- Muscle aches or joint pain
- Feeling tired
- Nausea/Vomiting
- Fever
- Chills

The most frequently reported side effect from other studies with the mRNA-1647 study vaccine is injection site pain. While all of the above side effects may be very common (greater than 10%) in participants who receive mRNA-1647, the other most frequently reported side effects from other studies with the mRNA-1647 study vaccine include:

- Headache
- Fatigue (tiredness)
- Muscles aches

• Chills

There have been a few participants from another mRNA-1647 study who reported temporary underarm gland swelling on the same side they received the mRNA-1647 study vaccine.

Most of these side effects occurred within the first few days after receiving the study vaccination and went away within a few days. Not everyone had these side effects and those who experienced them did not necessarily experience them after every dose. These side effects were usually reported as mild or moderate.

Brief increases in some laboratory tests, [including liver function tests and a digestive enzyme (lipase)], were noted in previous clinical studies with mRNA-1647 and similar vaccines. These increases were observed without physical symptoms or signs, and generally returned to levels observed before study vaccination. Significance of these observations is unknown.

Studies in mice and cells were performed for vaccines similar to the one being tested in this study. These studies looked for changes in DNA (genes), which is the material that determines inheritable traits and showed that the study vaccines did not have an effect on DNA. The mRNA vaccines do not change or interact with your own genetic make-up in any way.
If you had an allergic reaction after receiving any vaccination in the past or if you are allergic to any product(s), you must tell the study doctor or study staff before you decide to sign and date this informed consent form. Some symptoms of allergic reactions are:

• Rash
• Wheezing and difficulty breathing
• Dizziness and fainting
• Swelling around the mouth, throat or eyes
• A fast pulse
• Sweating

Severe, potentially life-threatening allergic reactions have been reported in participants who have received other mRNA vaccines. These severe reactions are very rare and typically occur immediately after vaccination. You will be monitored for at least 30 minutes after each study injection at the study site. Please seek treatment immediately and tell the study doctor and study staff if you have any allergic reaction symptoms during the study. If not treated promptly, an allergic reaction could become life-threatening. Medical treatment will be given to you in case of an allergic reaction to the study vaccine.

There have been very rare reports of myocarditis (inflammation of the heart muscle) or pericarditis (inflammation around the heart) in individuals receiving COVID-19 mRNA vaccines, which also use mRNA like the vaccine you would receive in this study. Most of the reports have occurred in young males following the second dose,

but cases have been reported in older males and in females as well, and also following the first dose. Symptoms of myocarditis or pericarditis include chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart, with onset of symptoms most commonly reported within a few days following vaccination. Study participants should seek medical attention and also notify study site staff if any of these symptoms occur following vaccination. Although long-term follow-up is limited, these are typically mild cases and individuals tend to recover within a short time following standard treatment and rest. It is not known whether the risk of myocarditis or pericarditis is increased following other mRNA vaccines.

You may have emotional stress if you experience any of the side effects listed above or from keeping to the study visit schedule. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may stop taking part in the study at any time.

You will be monitored for risks and side effects throughout your participation in the study. You should contact the study doctor if you think you are having side effects or experiencing a change in your medical condition.

Blood samples:
Taking a blood sample involves insertion of a needle into a vein in your arm and withdrawing a few tablespoons of blood. You may have pain, redness, irritation or bleeding where the needle is inserted. Some people may have a brief feeling of faintness. You may have pain or bruising for up to a few days where the needle was inserted after the blood draw. There is a rare possibility of infection where the needle is inserted.

Placebo risk:
If you receive placebo, you may experience similar side effects to those listed above. If given placebo, you will not develop an immunity to acquired CMV infection.

Unknown risks:
There may be possible side effects of the study vaccine that are not fully known. You may experience some side effects that have not been experienced before. This could be an allergic reaction or interaction with another drug. Medical treatment will be given to you in case of an allergic reaction to the study vaccine. It is important that you tell the study doctor about any changes in your health.

If you hold private medical or travel insurance, you may wish to check with the insurance company before agreeing to take part in this study as your taking part may affect the insurance.

Are there any reproductive risks?

The effect of the study vaccine used in this study on an unborn child is not known.

Women who are pregnant at the screening visit or on the day of the first injection (Day 1) will not be allowed to take part in the study. A pregnancy test will be done before

each study vaccination. If you become pregnant during the study, you must tell the study doctor immediately and you will not receive any additional study vaccinations, however, you will continue to be followed in the study. The study doctor will advise you about your health care and will ask about your pregnancy and its outcome. If you are in the seronegative group and you have not tested positive for CMV infection, you may be offered testing for CMV infection monthly during pregnancy. Your child should also be offered a CMV PCR test. Pregnancy safety and general outcome data may be collected beyond end of study (that is, for pregnancies continuing beyond the end of study visit).

If you become pregnant during the study, the study doctor will ask you if it is okay to collect details about your pregnancy and the health of your baby for scientific and safety reasons. You will also be offered another consent form to allow collection of data about the health of your baby and additional laboratory testing as part of separate substudy.

What are the possible benefits of taking part?

Taking part in this study may or may not help you prevent CMV infection. However, the data we get from you during this study may help doctors learn more about the study vaccine and disease, and this may help patients in the future.

You will receive testing related to your general health status as well as be informed of whether you have had prior CMV infection through the testing and evaluations associated with this study.

Will you be informed if new information becomes available during the study?

The study doctor will inform you in a timely manner of any new information that may affect your willingness to provide information. If you decide not to carry on, your study doctor will make arrangements for your care to continue. If you decide to continue in the study your study doctor may ask you to sign an updated information sheet and consent form.

What happens if you change your mind?

Your participation in the study is voluntary. You may decide not to participate, or you can leave the study at any time. If you leave the study early, data, including samples, obtained while you were in the study may still be kept with other data obtained as part of the study.

If you withdraw consent during the study, the study doctor and study staff will not collect additional data from you. Data already collected will be retained to ensure that the results of the research project can be measured properly and to comply with the law. Data collected by the Sponsor up to the time you withdraw will form part of the research project results.

Expenses and payments

You may be reimbursed for any reasonable expenses incurred as a result of taking part in this study on production of a receipt (examples include, but not limited to, meals/refreshments if your visit lasts over 3 hours, travel). In addition to this, as a recognition for your time dedicated to this study you will receive:
£20 for each completed onsite visit
£5 for each completed phone follow up visit and
£10 for each week of eDiary completion (7 days period of completed eDiary)

As a participant in this study, you may be provided with reimbursement of expenses and have transportation arrangements provided for you. Scout Clinical is the company hired by Moderna to arrange reimbursement and transportation for study participants to and from scheduled study visits, starting with the first vaccination visit (Day 1).

You may contact the study staff to request transportation provided by Scout Clinical. If you use this service, Scout Clinical will coordinate and pay for your transportation. Utilisation of the Scout Clinical portal for visit-related transportation is not required for participation in the study.

Reimbursement for completed visits may be made via cheque, or bank transfer. You will be paid within approximately 2 weeks following the completion of each study visit or activity.

If you have any questions regarding your compensation for participation, please contact the study staff.

Who is funding this research?

ModernaTX, Inc. (a pharmaceutical company) will be organising and funding this study. ModernaTX, Inc. will pay the study site to cover their costs of conducting this study. If applicable, your study doctor will disclose to you any financial links or other interests that he/she may have to the Sponsor.

What if there is a problem- Complaints

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions 02087255382 modernacmv@sgul.ac.uk. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. We recommend that you obtain a copy of your hospital's complaints procedure or policy if you intend to make a complaint.

Harm
If you are injured because of your participation in this study, you will be entitled to receive compensation in accordance with UK legislation. Please contact your study team if you feel this is the case.

ModernaTx, Inc. will provide compensation for any injury caused by taking part in this study in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI).

ModernaTx, Inc. will pay compensation where the injury probably resulted from:

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

Any payment would be without legal commitment. (Please ask if you wish more information on this)

Moderna, Tx, Inc. would not be bound by these guidelines to pay compensation where:

- The injury resulted from a drug or procedure outside the trial protocol
- The protocol was not followed.

In the unlikely event that something does go wrong and you are harmed during the research and this is due to someone's negligence, then you may have grounds for legal action for compensation against the NHS Trust, however you might need to pay your legal costs.

Copies of these guidelines are available from your study doctor on request.

How will your confidentiality be respected and the privacy of your personal information maintained?

The study site will record basic personal details about you, including your name, contact details, gender, height, weight and racial origin (to be used only for clinical purposes), as well as information on your medical history, and clinical data collected about your participation in the study. The following people may also access these records:

- Study monitors and auditors, who may work for ModernaTX, Inc. or its authorised agents, who check that the study is being performed correctly and that the information collected about you is accurate;
- National and international regulatory authorities involved in keeping research safe for participants;

To ensure privacy, your name and other directly identifying information will not be attached to records or samples released to ModernaTX, Inc. and its service providers for research purposes. Instead, you will only be identified by a code. Only the study doctor and authorised personnel will be able to connect this code to your name, by a list that will be kept securely by the study site for 2 years after the last marketing application approval. Your date of birth and initials may also be recorded to help identify your study record.

Your coded data will be forwarded to ModernaTX, Inc. and its service providers for activities related to the study e.g. laboratory analysis. A list of companies to whom

your coded information is transferred is available from the ModernaTX, Inc. via your study doctor.

Under the Data Protection Act 2018, the ModernaTX, Inc. makes important decisions on how your information collected for the research project are used and disclosed and is responsible as 'controller' for ensuring that the rules of this law are followed. The study site will have similar responsibility in respect to the handling of data in your medical files at site.

To the extent there is no conflict with the purpose of the study, you have the right to access, through your study doctor, all the information collected about you and, if applicable, ask for corrections. You may have the additional rights to object to how your information is being handled, request deletion of your data, or restrict aspects of the processing of your information. Note however, in order to protect the scientific integrity of the study, the treatment you receive in this study needs to remain unknown (= blinded) until the study data is analysed.

You also have the right to complain about how your information is handled to a supervisory authority that is responsible for enforcing data protection law. In the UK, this is the Office of the Information Commissioner.

Recipients of your information may be in countries that do not provide the same standard of legal protection for your information as in the United Kingdom, raising the risk that you will not be able to enforce the above rights and recipient organisations may not be legally required to fully secure your data. Certain international recipients of your information may have signed special contracts to provide legal protection for your transferred information (e.g. so called "Standard Data Protection Clauses"). In any event, all parties involved in the study are required to maintain your confidentiality.

Your information is collected, used and disclosed in the interest of ModernaTX, Inc. conducting scientific research. You are asked to consent to various uses and disclosures of your information at the end of this form.

If you should withdraw from the study, data collected prior to your withdrawal may still be processed along with other data collected as part of the study. Normally no new information will be collected for the study database unless you specifically consent to that. However, the law does require that any side-effects you may suffer are documented. You have the right to require that any previously retained samples are destroyed.

This study may only be performed by collecting and using personal information on study participants as described in this form, therefore you may only participate in the study if you agree to the collection and use of your information as described here.

If you have any questions, comments or complaints about how your information is handled in this study, or wish to obtain a copy of the Standard Data Protection Clauses, you should firstly contact your study doctor who will be able to direct your

query where appropriate to staff responsible for data protection at ModernaTX, Inc. or site, including the site Data Protection Officer.

FIRMA Clinical Research (Home Health Care Services)

During this study, you will have the option to have an experienced and licensed medical professional come to your home (or other convenient location) to complete certain study visits during Follow-up, rather than having to travel to a study site for those visits. The medical professional will have specific training for this study. If you agree to use the home health care services, a medical professional will contact you to schedule the visit(s). This could be the staff from the study site staff or professionals from home care agency.

To schedule the visit(s) in your home or other location, the medical professional, home care agency (Firma Clinical Research) and its subcontractors will have access to personally identifiable information about you to schedule the visit(s), including your name, date of birth, address, and telephone number.

During the visit(s), the medical professional will also collect health data that can identify you that is needed for the study, including a physical examination, vital signs, blood or urine samples, and changes in health or drugs. After each visit, you will be given the chance to give feedback on your experience in a survey. You do not have to complete the survey. If you choose to complete the survey, you do not need to give your name.

Because Firma Clinical Research provides many of these study-related services in the US, your information may be transferred or stored outside of the UK in the US or to other countries which the UK has determined provide less stringent privacy protection laws and which could participant your information to greater risk of unauthorised use or disclosure.

By placing your initials in the consent form below, it indicates that you agree to allow Firma Clinical Research to conduct home visits if needed. You do not have to consent to these visits. If you do not wish to agree to the visits, do not place your initials in the consent box as described.

If you do not agree to the study visits being conducted in your home or other location, you can still take part in this study by completing the required study visits at the study site.

Please speak with your study doctor to see if home visits are available at your study site.

Scout Clinical: EU General Data Protection Regulation

Your personal information collected to facilitate your participation in this study will only be used for the purpose of arranging Scout clinical services. Scout Clinical will not disclose your data to any third party unless in connection to one of these services and then only the specific data needed to provide the service will be shared. Only Scout Clinical employees that need access to your information to provide the services listed will have access to your data. Scout Clinical will only keep your personal data for the duration of the study. At any time, you may contact Scout

Clinical to ask to review the personal data we have collected or that your data be deleted, transferred, or corrected.

Scout Clinical: Information sharing and privacy
As a part of the study, Scout Clinical will collect information about you, including name, address, phone number, study appointment dates, date of birth, National Insurance number, email address, bank transfer instructions, and your study participant ID code.

Medable (Telemedicine)

This company will collect your name, mobile phone number, email address, and the password associated with the user account. This company will not have access to the content of the telemedicine visit. They also will not record the visit or the audio or any images created during the visit. The data collected by the telemedicine app will be stored on a server that is located in the US. It will only be stored on this server for as long as the study lasts.

What will happen to any samples I give?

Blood, urine and/or saliva samples will be taken from you in this study. Results of your samples will be used for research purposes only. You will not receive your results of the tests other than your initial screening test for CMV infection, and if you are in the seronegative group, you will be informed if you have a positive CMV test result. Your samples will be sent to a laboratory to be tested or stored prior to testing by special laboratories. Samples will be identified by a code and will not show who you are.

Your samples will be sent to following laboratory to be tested:

Region	**Name and address of laboratory**
EMEA only	PPD Central Laboratory Kleine Kloosterstraat 19 Zaventem, B-1932 Belgium

After the study tests are completed, some of your samples may be retained for up to 20 years and may be used for research purposes. The samples will remain the property of Moderna. You will not be told of additional tests, nor will you receive results of any of these tests. The Sponsor may continue using the coded study data and samples after the study is over. If you consent to this you are allowing the Sponsor to use the information and samples in the research and development of mRNA-1647 or other research purposes. You will not own any of the information or samples collected.

Urine dipstick pregnancy test will be performed during study visits. Urine samples for pregnancy testing will be destroyed after the test is performed. You will be informed of the pregnancy test results.

Has the study received medical or ethical approval?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your interests. This study has been reviewed and given favourable opinion by the London - South East Research Ethics Committee.

Involvement of the General Practitioner/Family doctor (GP)

Your general practitioner (GP) or family doctor will be notified of your involvement in this study. They will be asked to pass relevant information about your health status and medication changes to the study doctor.

Who can you contact with further questions?

You may ask questions about this Information sheet or the study at any time (before or during the course of the study). If you have additional questions, a complaint about any part of this study, or experience a research-related injury, contact the study doctor Dr Drysdale or the study support staff on 02087255382 modernacmv@sgul.ac.uk who will do their best to help.

If you suffer a serious illness or injury during this study, please contact the study doctor immediately. You should also inform the medical staff treating you that you are participating in this research study and contact your GP.

For any questions about your rights as a research participant, please direct enquiries to:
PALS: https://www.stgeorges.nhs.uk/patients-and-visitors/help/

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

After this study is over, a brief report of the overall results will be prepared for the general public. The study results may also be shared with scientific journals and the scientific community. Whenever the results of the study are shared or published, your identity will remain private.

Can I share information about the study?

If you participate in this study, you should feel free to discuss the study with your family and with other people who are close to you. It is recommended to tell your health care provider about your participation in the study. However, to help make sure that the information from the study is as accurate and reliable as possible, please do not discuss information about the study in public places while the study is in progress.

Public places include things like social media (Facebook, Instagram, Twitter), blogging, and speaking to the media.

CONSENT FORM

Principal Investigator: Dr Simon Drysdale **Participant Initials:**

Participant Number:

Short Title: mRNA-1647 vaccine for Cytomegalovirus (CMV)

Statement of Consent	*Please initial box:*
I confirm that I have read and understand the participant information sheet for the above study. I have had the opportunity to consider the information, ask questions and I am satisfied with the explanations provided	
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care or legal rights being affected	
What will happen to your data? By signing this form you provide consent for your information to be collected, used and shared as described: • The authorised representatives of ModernaTX, Inc., and regulatory authorities' inspectors may have direct access to your medical records. • Study data, including your coded medical information, may be retained and later used for further research into your medical indication, unless you object. • Study data may be transferred to other countries for study purposes, including countries not providing the same standard of legal protection for your personal information as in the United Kingdom.	
I specifically agree to my personal information and blood samples collected during the study being sent outside the UK as described in this information sheet	
I agree to my GP being informed of my participation in the study as described in this information sheet	
I understand that I will receive a copy of this signed and dated information sheet and consent form	
I voluntarily agree to take part in this study	

Optional - As outlined in the section 'FIRMA Clinical Research (Home Health Care Services)' FIRMA Clinical Research is being used for home visits. I would like to receive home visits and therefore agree and understand that the company will have access to my name and other study related data as described in this section (only initial this section if you agree to this).	
Optional Future use of Samples: I agree that my coded data and biological samples may be used in addition to this study for future research **RELATED** to CMV disease and mRNA-1647 vaccine. **Yes ☐ No ☐**	
Optional Future use of Samples: I agree that my coded data and biological samples may be used in addition to this study for future research **NOT RELATED** to CMV disease and mRNA-1647 vaccine. **Yes ☐ No ☐**	
I give permission for personal information to be shared with Scout Clinical (third party) as outlined in the 'Expenses and Payments' section of this information sheet. **Yes ☐ No ☐**	
I give permission for my study doctor to contact my GP and request my medical records during my participation of this study. **Yes ☐ No ☐**	

Participant Consent UK (continued)

Participant:

_____

Printed Name, in full

_____

Signature of Participant **Date (dd-mmm-yyyy)**

- I have presented the study and answered the participant's questions.
- I will give the participant a copy of this signed and dated informed consent form.

Person Obtaining Consent (Study Doctor or Delegate):

_____

Printed Name, in full

_____

Signature of Person Obtaining Consent **Date (dd-mmm-yyyy)**

when complete: 1 for participant, 1 for researcher site file; 1 to be kept in medical notes

Appendix 1 - Schedule of Assessments for Seronegative & Seropositive groups:

Visit	Visit Type	What will be done
Screening Visit (around 2h)	In-person* *Where permitted, a portion of this visit may be done via telemedicine.	• You will be asked to provide informed consent • Demographic data • Medical history review, including pregnancy history • Medication review, including prior vaccinations • Physical examination, height and weight • Vital signs • Blood sample to confirm if you had prior CMV infection • Urine pregnancy test
Day 1 (around 2h)	In-person	• Medication review and check if you have received any nonstudy vaccination(s) • Discussion of any changes in your health since the last visit • Confirmation that you may participate in the study after review of these medication and health updates • Physical examination (based on reported symptoms) • Blood sample collection for immune response (how your body reacts to foreign substances) to CMV • Urine pregnancy test • Breastfeeding status • Vital signs before and after your study vaccination • Blood sample to check for CMV infection (seronegative group only) • Urine sample to check for presence of CMV in urine (seropositive group) • 1st study vaccination • You will receive instruction from the study staff on how to complete the eDiary • You will be asked to make your first eDiary entry to check if you have experienced any adverse effects •
Day 8 (around 15 minutes)	Safety telephone call	• Medication review and check if you have taken any non-study vaccination(s) • Discussion of any changes in your health since the last visit • Review any adverse effects after study vaccination, if any of the side effects lasted beyond 7 days of receiving the study vaccination, and if you had to take medications for treatment of these side effects, or if you are missing entries in your eDiary.
Month 1 (Day 29) (around 15 minutes)	Safety telephone call	Please refer to procedures described at visit "Day 8
Month 2 (Day 57) (around 2h)	In-person	• Medication review and discussion of any changes in your health since the last visit • Physical examination (based on reported symptoms) • Vital signs before and after your study vaccination • Urine pregnancy test • Breastfeeding status • 2nd study vaccination • Blood sample to check for CMV infection (seronegative group only) • Urine sample to check for presence of CMV in urine (seropositive group) • You will be asked to make an entry in eDiary after second study vaccination to check if you have experienced any adverse effects

Day 64 (around 15 minutes)	Safety telephone call	Please refer to procedures described at visit "Day 8
Month 3 (Day 85) (around 1h)	In-person	• Medication review and check if you have taken any nonstudy vaccination(s) • Discussion of any changes in your health since the last visit • Blood sample collection for immune response (how your body reacts to foreign substances) to CMV • Physical examination (based on reported symptoms) • Vital signs • Urine pregnancy test • Blood sample to check for CMV infection **(seronegative group only)** • Urine sample to check for presence of CMV in urine **(seropositive group or seronegative group following CMV infection)** • To check if you have experienced any adverse effects • If you are in the seronegative group and experienced symptoms of possible CMV infection, you will undergo Illness Assessment visit, and you may receive two questionnaires via eDiary to assess your health status and impact of illness on your daily activities depending on timing of symptoms and availability of the questionnaires. You may be requested to complete the questionnaire more than once.
Month 4 (Day 113) **Month 5 (Day 141)** (around 15 minutes)	Safety telephone calls	• Discussion of any changes in your health since the last visit • Review of medications • To check if you have taken any nonstudy vaccination • If you are in the seronegative group and experienced symptoms of possible CMV infection, you will be asked to undergo Illness Assessment visit (unscheduled visit), and you may receive two questionnaires via eDiary to assess your health status and impact of illness on your daily activities depending on timing of symptoms and availability of the questionnaires. You may be requested to complete the questionnaire more than once.
Month 6 (Day 169) (around 2h)	In-person	Please refer to procedures at visit "Month 2 Day 57" • 3rd study vaccination • You will be asked to make entry in eDiary after the third study vaccination • If you are in the seronegative group and experienced symptoms of possible CMV infection, you will undergo Illness Assessment visit, and you may receive two questionnaires via eDiary to assess your health status and impact of illness on your daily activities depending on timing of symptoms and availability of the questionnaires. You may be requested to complete the questionnaire more than once.
Day 176 (around 15 minutes)	Safety telephone call	Please refer to procedures described at visit "Day 8"
Month 7 (Day 197) (around 1h)	In-person	• Medication review and check if you have taken any nonstudy vaccination • Discussion of any changes in your health since the last visit • Blood sample collection for immune response (how your body reacts to foreign substances) to CMV • Physical examination (based on reported symptoms) • Vital signs • Urine pregnancy test • Blood sample to check for CMV infection **(seronegative group only)**

		• Urine sample to check for presence of CMV in urine **(seropositive group or seronegative group following CMV infection)** • If you are in the seronegative group and experienced symptoms of possible CMV infection, you will undergo Illness Assessment visit, and you may receive two questionnaires via eDiary to assess your health status and impact of illness on your daily activities depending on timing of symptoms and availability of the questionnaires. You may be requested to complete the questionnaire more than once.
Month 8 (Day 227) **Month 9 (Day 257)** (around 5 minutes)	eDiary	• Safety eDiary will ask you to report if you have experienced any safety events. If you report any safety event in the eDiary or if you do not respond to prompts to complete the eDiary, a study staff member will contact you by telephone to check if you have experienced any events or symptoms during follow-up • If you are in the seronegative group and experienced symptoms of possible CMV infection, you will be requested to undergo Illness Assessment visit, and you may receive two questionnaires via eDiary to assess your health status and impact of illness on your daily activities depending on timing of symptoms and availability of the questionnaires. You may be requested to complete the questionnaire more than once.
Month 10 (Day 287) (around 1h)	In-Person	• Discussion of any changes in your health since the last visit and related medications • Physical examination (based on reported symptoms) • Urine pregnancy test (female participants only) • Blood sample to check for CMV infection **(seronegative group only)** • Urine sample to check for presence of CMV in urine **(seropositive group or seronegative group following CMV infection)** If you are in the seronegative group and experienced symptoms of possible CMV infection, you will undergo Illness Assessment visit, and you may receive two questionnaires via eDiary to assess your health status and impact of illness on your daily activities depending on timing of symptoms and availability of the questionnaires. You may be requested to complete the questionnaire more than once.
Month 11 (Day 317) (around 5 minutes)	eDiary	Please refer to procedures at visit "Month 8 (Day 227)"
Month 12 (Day 347) (around 1h)	In-person	Please refer to procedures at visit "Month 7 (Day 197)".
Month 13 (Day 377) **Month 14 (Day 407)** **Month 16 (Day 467)** **Month 17 (Day 497)** **Month 19 (Day 557)** **Month 20 (Day 587)** **Month 22 (Day 647)** **Month 23 (Day 677)** **Month 25 (Day 737)** **Month 26 (Day 767)** **Month 28 (Day 827)** **Month 29 (Day 857)** (around 5 minutes)	eDiary	• Safety eDiary will ask you to report if you have experienced any safety events. If you report any safety event in the eDiary or if you do not respond to prompts to complete the eDiary, a study staff member will contact you by telephone to check if you have experienced any events or symptoms during follow-up • If you are in the seronegative group and experienced symptoms of possible CMV infection, you will be requested to undergo Illness Assessment visit, and you may receive two questionnaires via eDiary to assess your health status and impact of illness on your daily activities depending on timing of symptoms and availability of the questionnaires. You may be requested to complete the questionnaire more than once.

Month 15 (Day 437) **Month 18 (Day 527)** **Month 21 (Day 617)** **Month 24 (Day 707)** **Month 27 (Day 797)** (around 1h)	In-person	• Discussion of any changes in your health since the last visit and related medications • Physical examination (based on reported symptoms) • Urine pregnancy test (female subjects only) • Blood sample collection for immune response (how your body reacts to foreign substances) to CMV (at Month 18 and Month 24 visits) • Blood sample to check for CMV infection (seronegative group only) • Urine sample to check for presence of CMV in urine (seropositive group or seronegative group following CMV infection) • If you are in the seronegative group and experienced symptoms of possible CMV infection, you will undergo Illness Assessment visit, and you may receive two questionnaires via eDiary to assess your health status and impact of illness on your daily activities depending on timing of symptoms and availability of the questionnaires. You may be requested to complete the questionnaire more than once.
Month 30 (Day 887) (around 1h)	In-person	• Discussion of any changes in your health since the last visit and related medications • Physical examination (based on reported symptoms) • Urine pregnancy test • Blood sample collection for immune response (how your body reacts to foreign substances) to CMV • Blood sample to check for CMV infection **(seronegative group only)** • Urine sample to check for presence of CMV in urine **(seropositive group or seronegative group following CMV infection)** • Study completion