PATIENT INFORMATION AND CONSENT
TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Study Title:	Immunogenicity of vaccine VLA2001 compared to AZD1222. The COV-COMPARE trial. This trial is comparing the immune responses of the investigational vaccine VLA2001 with the licensed AZD1222 vaccine from Astra Zeneca against COVID-19.
Study Number:	VLA2001-301
Principal Investigator (study doctor):	*<<name>>* *<<Institution>>* *<<Address>>* *<<Telephone Number>>* *<<Emergency and/or Other Contact(s) required by IRB/IEC>>*
Sponsor (a for-profit drug company):	Valneva Austria GmbH Campus Vienna Biocenter 3 A-1030 Vienna, Austria
CRO (company helping to manage the study)	Pharm-Olam LLC 1st Floor, One Station Square Bracknell, Berkshire RG12 1QB United Kingdom

You are being asked to participate in a research study. This consent form gives you important information about this study to help you decide whether you want to participate or not. It describes the purpose of this study, the study procedures, the possible risks, and provides information about your rights as a study participant.

Please take the time to read this information carefully. You should talk to the study doctor and his/her study staff about this study and ask any questions you have. You can also discuss this study with other people such as your primary care physician or a specialist in charge of your medical care. If you decide to participate in this study, you will be asked to sign and date this form. You will receive a copy of the signed form.

After you sign this form, the study doctor and his/her study staff will do some tests to see if you meet the study requirements. If you have a different primary care physician or a specialist in charge of your medical care, the study doctor will ask if he/she can tell that person about your participation in this study. Your GP will be asked to inform the study doctor of any adverse events he/she becomes aware of while you are on the study.

Your participation in this study is voluntary. You are free to say yes or no. If you do not want to participate, your regular medical care and legal rights will not be affected. You may stop participating in this study at any time, without giving a reason.

Valneva Austria GmbH is conducting this study and the study is being paid for by the UK government. Pharm-Olam LLC is working with Valneva Austria GmbH to help manage this study.

The sponsor will ensure that the most up to date guidelines are being adhered to during the conduct of this study.

1. WHAT SHOULD I KNOW ABOUT THIS STUDY?

1.1 Why is this study being done?

The purpose of this study is to compare the study drug, called VLA2001 with the licensed vaccine AZD1222 from Astra Zeneca in terms of safety and measures of the immune response against COVID-19 disease. Unlike some other vaccine trials where people receive trial vaccine or a placebo injection, everyone in this study will receive a COVID-19 vaccine and the main outcome being measured is the immune response, not the occurrence of disease, alongside rates of any common side effects.

1.2 What is the drug being tested?

VLA2001 is a highly purified, inactivated vaccine. An inactivated vaccine is a vaccine consisting of virus particles that have been grown in culture and prepared in a way that they lose their disease producing capacity, but allow your body to recognize the coronavirus and defend itself against COVID-19 disease. The virus strain used in this vaccine was derived from a Chinese tourist from Hubei who was diagnosed in a hospital in Rome, Italy.

AZD1222 is a vaccine derived from genetically modified chimpanzee virus. This virus is a vector and was modified so that it can produce a part of the coronavirus. The introduced part of the virus is the spike protein, an external component of the virus particle that enables the SARS-type coronavirus to enter cells. Producing it following vaccination will prompt the immune

system to attack the coronavirus through antibodies and T-cells if it later infects the body. The vaccine was developed by AstraZeneca. AZD1222 was approved for use in the UK in December 2020.

You will receive 2 doses of vaccine 4 weeks apart. If you are under 30 years of age you will receive VLA2001. If you are 30 years and older, you will receive either VLA2001 or AZD1222 but neither you nor the study team will know which vaccine you received.

The vaccine will be administered as an intramuscular (into a muscle in your arm) injection. Although COVID-19 vaccines have been offered in the national roll-out 12 weeks apart in order to immunise as many people at high risk of severe disease as quickly as possible, studies have shown high levels of protection are provided after a shorter dose interval like the one which will be used in this study. AZD1222 will be given in a four weeks interval to match the VLA2001 vaccination schedule.

1.3 How many people will take part in this study?

You will be 1 of up to 4000 participants participating in this study at approximately 27 hospitals and clinics in the UK.

1.4 How long will I be participating in this study?

You will take part in this study for up to 13 months. There will be a total of 7 or 8 visits for all participants. There may be additional appointments that you will need to attend if you develop any symptoms which may indicate you have a COVID-19 infection.

1.5 What are the chances that I will get VLA2001?

If you are under 30 years of age you will receive VLA2001. If you are 30 years and older, receiving VLA2001 or AZD1222 is decided randomly, like flipping a coin. In this age group, 2 in 3 participants will receive VLA2001 and a 1 in 3 will receive AZD1222. The reason for this is that this will allow for the correct number of people to receive each of the two vaccines for the study to provide the necessary information on the comparison of the immune responses and the identification of common side-effects required by the medicines regulator (the MHRA).

1.6 Will I know which study drug I am receiving?

If you are under 30 years of age, you will receive VLA2001.

If you are 30 years and older, neither you nor your study doctor nor his/her study staff will know which study vaccine you are receiving. In an emergency, the study doctor can find out what you have received.

1.7 Can I stop participating in the study?

You are free to stop participating in this study at any time. If you stop, you will not lose any medical benefits except for any benefits that you might have been receiving in connection with this study. All information and samples collected from you before you stop the study may still be used by Valneva Austria GmbH to understand more about the study vaccines.

If you want to stop participating in the study, please tell the study doctor. He or She can tell you about stopping all or part of the study activities. You can stop taking part in the study at any time with no need to give reasons for your decision.

Also the study doctor or Valneva Austria GmbH may stop your participation at any time. The study doctor will tell you if this happens. Some reasons this could happen include:

- Staying in the study could be harmful to you.
- You are not able to complete the study procedures as required.
- The study is stopped by Valneva Austria GmbH for reasons not related to you.

There may be other reasons to stop your participation in this study that are not known at this time. If you stop participating in the study, or the study ends, you will not receive your second dose of vaccine and you may be asked to come back for final tests and procedures.

If you stop participating in the study, any personal data collected before your stopping may still be processed along with other data collected as part of the clinical trial.

1.8 Whom should I contact if I have questions about the study?

If you have questions about the study, or have a problem related to the study, you may contact the investigator at the telephone number below.

Name: _____ Telephone: (_____) _____

If you are calling after hours or on a weekend, you may contact

Name: _____ Telephone: (_____) _____

If you have questions about your rights as a research participant, you should contact the individual below.

<<Insert name of Patient Advice and Liaison Service, address, and telephone number>>

Name: _____ Telephone: (_____) _____

Address: _____

All spoken and written information and discussions about this study will be in a language that you understand.

2. WHAT WILL HAPPEN IF I PARTICIPATE IN THE STUDY

2.1 What am I expected to do if I take part?

If you agree to take part in this research study, you will be asked to sign this Research Ethics Committee (REC)-approved informed consent form and you must meet specific entry criteria for the study.

While participating in this study, you must return for clinical visits.

You will be asked to give a medical/surgical history (including vaccination history), and your body weight and height will be recorded. Your vital signs (blood pressure, pulse [how many times your heart beats per minute] and body temperature) will be taken at several times.

You will be asked to provide blood samples for laboratory safety tests, COVID-19 virus testing, as well as urine samples for a dip stick test and for all women who are able to have children, pregnancy tests.

You will need to complete an eDiary (an electronic app used on your mobile phone) where you enter details related to any side effects you may experience after vaccination or in case you experience COVID-19 symptoms. You will have to answer questions about how you are feeling. This will be completed by you at home for 7 days after each vaccination. Some of the questions

will ask you to enter your daily oral temperature and to measure the size of the area where you received the vaccination (if there is redness or swelling). The study team will help you to download, install and become familiar with the app and will provide you with a measuring ruler (to measure any reactions at the injection site) and an oral thermometer (to measure your temperature).

A randomly selected subset of 1200 participants will attend one additional visit at Day 8 (Visit 2). Blood sampling will take place at this visit for current health testing and, if you are over 55 years of age, immune response testing.

Should you experience any of the following COVID-19 symptoms during the study conduct, please contact your study site:

Immediately: You should contact the study site immediately, in case you develop any of the following symptoms;

- Fever (body temperature ≥38.0°C or ≥100.4°F), or
- Shortness of breath, or
- Difficulty in breathing

After 2 consecutive days: You should contact the study site in case you have at least one of the following symptoms, for at least 2 consecutive days:

- Sore throat
- Chills
- Cough
- Fatigue
- Muscle aches
- Body aches
- Headache
- New loss of taste
- New loss of smell
- Nasal Congestion
- Runny nose
- Nausea
- Vomiting
- Diarrhoea (loose stools)

If you have confirmed COVID-19 symptoms, you will be tested on site to check if you do have a COVID-19 infection or not (PCR test).

If the test is negative, you will have a second PCR test on site after 2 days. If the result is still negative, you will continue with the scheduled visits as planned.

If either test is positive, you will come on site to perform a COVID-19 illness visit. As part of these visits, a nasal swab or saliva sample, and a blood sample to check your immune response will be taken. Standard, approved infection control procedures will be followed at all times.

You may contact your study doctor should you have any queries or need help.

Your current medications will be reviewed by the study doctor. You should consult with the study doctor about any medications you are taking. You should not have received any vaccine within 28 days prior to study enrolment (except for the flu vaccine). You should not have received immunoglobulin or another blood product within 3 months prior to vaccination or expect to receive immunoglobulin or another blood product during the study.

It is very important that you let the study doctor know what medications you are currently receiving or have received recently. It is also very important that you let the study doctor or study staff know before you take any new medications during the study, including any changes to your current medications.

Please be honest regarding your medical and medication history throughout the study and report any new information to the site staff at each visit. Giving false, incomplete, or misleading information about your medical history, including past and present medication use, may have serious health consequences.

You will be asked to come to the research facility for multiple visits as listed in Table 2.1.

Table 2.1 Study Visits

Study Period	Visits Occur
Screening	1 time
Scheduled Study visits at the site	6 or 7 times (depending on whether you attend Visit 2 or not)
Unscheduled study visits	As required or if necessary
Unscheduled PCR Visits	As required for any suspected COVID-19 infections
COVID-19 illness visits	As required for any confirmed COVID-19 positive participants

2.2 What types of tests or procedures will be involved with this study?

If you decide to participate in the study, some tests will be done to see if you are eligible. If the test results show that you meet the study requirements, then you will be able to start receiving the study vaccine. If the test results show that you do not meet the study requirements, you will not be able to start receiving the study vaccine.

As part of your participation in this study, you will have tests or procedures at each visit as shown in Table 2.2.

Table 2.2 Planned Procedures

Test/Procedure	Screening (Visit 0)	Baseline (Visit 1)	Schedule Study Visits
Physical examination	1 time	1 time	5 or 6 times - once at each visit (depending on whether you attend Visit 2 or not)

Test/Procedure	Screening (Visit 0)	Baseline (Visit 1)	Schedule Study Visits
Vital signs	1 time	1 time	1 time (Visit 3)
Pregnancy test (women who can have children)	0	1 time	1 time (Visit 3)
Blood draws to check your current health (safety lab)	1 time	0	0 *1 time if you are asked to attend Visit 2*
Prick test to check presence of COVID-19 antibodies	1 time	0	0
Swab collection from the nostril to check if an active COVID19 infection is present		1 time	0
Blood draws to check your immune response e.g., the production of antibodies (immunogenicity)	0	1 time	5 or 6 times - once at each visit (depending on whether you attend Visit 2 or not)
Blood draws to check the selectivity of your immune response (PBMC)* *Only for 200 selected subjects	0	1 time	5 times (Visits 3, 4, 5, 6, and 7)
Assessment of side effects	0	1 time	Throughout
Recording medications	1 time	1 time	Throughout

The Screening Visit and the Baseline Visit might be conducted on the same day.

If you contract COVID-19, you will return to the study site or have a home visit conducted for additional procedures where the following will occur: physical examination, blood samples will be collected from you to check your health and immune response and a nasal swab and saliva sample will also be collected. You will be asked about your medications and how you are feeling.

A baseline blood (about 10.0 mL for safety tests) and urine sample will be collected at Visit 0 (Screening visit) for standard clinical chemistry, haematology, blood clotting, and urinalysis. More blood may be collected from you if additional follow-up is needed for your safety. These blood samples will be used to monitor your health and safety and the effects of VLA2001.

Valneva Austria GmbH will not use your blood for any other tests without your permission. No one other than the Sponsor (and/or people or companies that the Sponsor works with) will test your samples. All your samples will be labelled with a special code. Only the study doctor and his/her study staff will be able to link your samples to you. All information obtained from your samples will be kept confidential as stated in the privacy and confidentiality section of this form.

Your signature at the end of this form means that you allow the study doctor and his/her study staff to complete the set plan of study procedures (called a study protocol), including the collection of samples. Your signature also allows Valneva Austria GmbH and its authorized representatives (including contractors) to use these samples for tests outlined in the study protocol or for tests necessary to ensure your safety.

You can ask the study doctor or his/her study staff about the tests listed in the study protocol. The study doctor may ask you to come back for additional safety tests after the end of the study.

2.3 What will happen to samples taken from me?

In addition to the research you are consenting to under this research study, Valneva Austria GmbH would like to store your blood samples for 15 years for future research at locations of contracted partners of Valneva either in UK, North America, or European region. With your permission, samples obtained can be kept indefinitely after end of study for potential future testing. If you agree to permit your samples to be analysed in the future, the results will not be provided to you.

You will not benefit directly from the research on your samples. The benefits of research using your samples include learning more about the body's response to the vaccination with VLA2001 as well as other aspects of immunity and other infections. In some research, using the sample may help researchers develop new medical tests or treatments that have commercial value. You will not receive any compensation that may result from any such commercial tests or treatments.

The sample will be stored in a confidential, safe, and secure manner using an ID code that relates to the vaccine and the time the sample was taken. No laboratory workers will have access to your name or medical records. These samples cannot be linked back to you by the testing laboratory.

2.4 Will I have to pay to take part in this study?

There will be no charge for your participation in the study.

You will be compensated for the time and trouble involved in your participation in this study.

If you are selected for participation, you may receive the below listed compensation for taking part in this research study. You may receive up to £600.00 (if you are required to attend Day 8) or up to £550.00 (if you are not required to attend Day 8) if you finish all the study visits and contacts.

If you are unable to complete all the study visits or decide not to take part in the study anymore, you will only be paid for the visits you finished. The compensation you will receive will be broken down as follows:

Study Payment Schedule	
Screening	£50.00
Day 1 (Vaccination I)	£100.00
Day 8 (applies only for the subset of 1200 participants)	£50.00
Day 29 (Vaccination II)	£100.00
Day 43	£50.00
Day 71	£50.00
Day 208	£100.00
Day 365	£100.00
Total:	**£600.00**

In addition, you will receive £50.00 for each unscheduled visit (e.g., COVID-19 illness-related visit or rescreening).

The schedule of payments will be discussed with you during the Screening visit. If for any reason you choose to discontinue or are withdrawn from the study, you will be compensated for each completed visit. If you do not meet the criteria for the study at the screening visit and are not able to take part in the study, you will be compensated only for that visit.

2.5 What if new information becomes available?

You will be informed of any new findings related to the vaccine you are taking during this study. These findings may affect your willingness to participate or to continue to participate in the study.

3. POTENTIAL RISKS AND DISCOMFORTS

3.1 Are there any risks from taking part in this study?

There may be risks to being in this study, from study vaccine, from some of the procedures or tests done in this study.

Your well-being and safety will be thoroughly monitored throughout the study. Please tell the study doctor or study staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the study, whether you think these problems are related to the study vaccine.

Ask the study doctor if you have questions about the signs or symptoms of any side effects that you read about in this consent form.

Possible risks that are frequently associated with any vaccination are:

- The occurrence of reactions around the vaccination site, for example local pain (pain without touching) or tenderness (pain upon touching), redness, swelling, itching, hardening, warmth

- As well as general symptoms like headache, nausea/ vomiting, tiredness, muscle pain, joint pain, feverishness or fever, rash, flu-like symptoms, chills, malaise (a general feeling of being unwell)

A group of medical doctors who are independent from the sponsor are overseeing the side effects in this study and can interrupt the study if needed.

All participants will be observed at the study site for at least 30 minutes after vaccination to ensure immediate treatment in case of side effects. The first 10 participants who are older than 55 years will be observed for at least 60 minutes after each vaccination.

3.2 What are the likely risks with VLA2001?

The study sponsor has conducted one clinical study with VLA2001. So far, 153 healthy volunteers aged 18 to 55 years have been given this vaccine candidate at different dose levels.

Thereof, 51 were given the dose level of the vaccine tested in this study. Overall, the study showed that VLA2001 was safe and well-tolerated at all dose levels tested. A description of the most frequent side effects (observed in at least 1 out of 10 study participants) that were observed following vaccination and how common they were, is given below. Overall, about seven of 10 volunteers in the first study noted any side effects.

Most Common side effects (affected more than 6 out of 10 study participants)

- Vaccination site tenderness (pain upon touching)

Medium Common side effects (affected 3 to 6 out of 10 study participants)

- Vaccination site pain
- Headache
- Tiredness
- Muscle Pain

Less Common side effects (affected 1 to 3 out of 10 study participants)

- Nausea/ vomiting

The majority of events was considered mild and moderate and resolved within a few days. Only two study participants had reported severe side effects (one subject reported severe tiredness for a single day; one subject reported severe tiredness and headache for a single day). The type and frequency of side effects reported following the first and second vaccination were comparable.

3.3 What are the likely risks with AZD1222?

The overall safety of COVID-19 Vaccine AstraZeneca (AZD1222) is based on an interim analysis of data from four clinical trials conducted in the United Kingdom, Brazil, and South Africa. At the time of analysis, 23,745 participants ≥18 years old had been randomized and received either AZD1222 or control. Out of these, 12,021 received at least one dose of AZD1222. Overall, among the participants who received AZ1222, approximately 9 of 10 participants were aged 18 to 64 years and approximately 1 of 10 was 65 years of age or older.

Most Common side effects (affected more than 6 out of 10 study participants)

- Vaccination site tenderness (pain upon touching)

Medium Common side effects (affected 3 to 6 out of 10 study participants)

- Vaccination site pain
- Headache
- Tiredness
- Muscle Pain
- Malaise
- Feverishness or fever ≥38°C

- Chills

Less Common side effects (affected 1 to 3 out of 10 study participants)

- Joint pain
- Nausea

The majority of side effects were mild to moderate in severity and usually resolved within a few days of vaccination. When compared with the first dose, side effects reported after the second dose were milder and reported less frequently. Side effects were generally milder and reported less frequently in older adults (≥65 years old).

Rare cases of severe and sometimes life-threatening thrombosis (blood clotting) inside blood vessels in different parts of the body including the brain, associated with low numbers of circulating platelets (small blood cells involved in the process of blood clotting) have been described in people during the period after they received AZ1222. As these events are very rare, it is very unlikely that any case would occur in this study. Since COVID-19 remains a risk now and in the coming months and may cause severe illness, including thrombosis and death, the balance of risk and benefit is considered to be strongly in favour of receiving this vaccine.

The MHRA advises that the benefits of vaccination continue to outweigh any risks but that careful consideration be given to people who are at higher risk of specific types of blood clots because of their medical condition.

The Joint Committee on Vaccination and Immunisation (JCVI) has weighed the relative balance of benefits and risks and advises that the benefits of prompt vaccination with the AstraZeneca COVID-19 vaccine far outweigh the risk of adverse events for individuals 30 years of age and over and those who have underlying health conditions which put them at higher risk of severe COVID-19 disease. JCVI currently advises that it is preferable for adults aged <30 years without underlying health conditions that put them at higher risk of severe COVID-19 disease, to be offered an alternative COVID-19 vaccine, if available. If you are 29 years of age or younger, you will not be able to receive the AstraZeneca COVID-19 vaccine as part of this trial.

The study team will be available to respond to any concerns and ensure correct investigations and treatment are provided to study participants if they develop any symptoms of illness of any kind throughout the period of participation and follow up.

3.4 What are the risks of using VLA2001 or AZD1222 in combination with other drugs?

Tell the study doctor or his/her study staff about any drugs you are taking, have taken recently, or are planning to take, including herbal medicines, supplements, and drugs you take without a prescription. The side effects of using VLA2001 or AZD1222 in combination with other drugs are unknown currently. Please discuss any concerns you may have with the study doctor.

<u>Other Side Effects:</u>

As with all research studies, the study vaccines and study procedures in this investigation may involve unknown risks. All medications can have both temporary and permanent side effects and can cause unforeseen adverse reactions.

As with any vaccine, the study vaccine might cause allergic reactions, including life-threatening allergic shock (anaphylaxis). Allergic reactions may occur even if one has never been in contact

with the substance before. You will be observed at the research site for 30 minutes after vaccination to guarantee immediate treatment in case of possible symptoms.

Some things that happen during an allergic reaction that could be a sign or symptom of a life-threatening allergic reaction (anaphylaxis) are:

- Rash (hives)
- Fast pulse
- Sweating
- A feeling of dread
- Swelling around the eyes and mouth
- Swelling of the throat
- Wheezing
- Having a hard time breathing
- A sudden drop in blood pressure (making you feel dizzy or lightheaded)
- Inability to breathe without assistance

You should get immediate medical help and contact the study doctor or study staff if you have any of these symptoms during the study.

3.5 What are the risks associated with procedures done in this study?

Blood Samples:

You will have your blood taken during the study. Possible side effects of having blood taken are tenderness, pain, bruising, bleeding and/or infection where the needle goes into the skin and vein. Having your blood taken may also cause you to feel sick and/or lightheaded.

Nasal Swab Sample:

You may feel discomfort when the swab is inserted into your nose. You may flinch, have watery eyes, or cough. You also may have dryness, pain, or bleeding because of the sample collection process.

3.6 Could VLA2001 or AZD1222 be harmful to an unborn or breastfed baby?

It is not known if VLA2001 or AZD1222 is harmful to an unborn or breastfed baby.

Female Participants:

Although risks of injury to an unborn child are unknown at this time, it is customary to take precautions in studies of this kind and only administer vaccines to pregnant women once there is experience of use and evidence of safety in non-pregnant individuals.

If you become pregnant during this study, potential risks could include the loss of the pregnancy (a miscarriage) or birth defects. The chance of this happening is unknown at this time. However, in trials like this, pregnant women and women planning to become pregnant cannot participate in this study.

If you could become pregnant (that is, you are not postmenopausal or have not had surgery to remove your: uterus, both ovaries, or both fallopian tubes), you should let your sexual partner know you are in this study and you should use acceptable methods of effective birth control during the study up to 3 months after the last dose of vaccine.

You must have a negative pregnancy test prior to enrolment if you are a woman who is able to have children.

Highly Effective Methods of Birth Control include:

- Hormonal oral (in combination with male condoms with spermicide), transdermal, implant, or injection, barrier (i.e., condom, diaphragm with spermicide)
- Intrauterine device (IUD)
- Vasectomy in the male sex partner at least 6 months prior to first vaccination

If you practice true abstinence because of a lifestyle choice (not just to participate in this study) you are exempt from contraceptive requirements. Periodic abstinence (e.g., calendar ovulation, symptothermal, post-ovulation methods) and withdrawal are NOT acceptable methods of contraception. If you are abstinent at the time of signing this document and you become sexually active, you must agree to use contraception as described in this section.

Male Participants:

If you are a sexually active male, you must take appropriate actions to avoid pregnancy with any partner (acceptable methods of effective birth control as mentioned above). Sexual intercourse with female partners who are pregnant, or breastfeeding should be avoided unless you use condoms starting with the first dose of study vaccine until 3 months after you receive your last dose.

3.7 What if my partner or I become pregnant during the study?

Females

If you become pregnant or think you are pregnant during this study, please tell the study doctor or his/her study staff right away. Further doses of the study vaccine, if scheduled, will not be given. The study doctor will notify Valneva Austria GmbH of the pregnancy, discuss any follow-up with you, and ask you for information on the pregnancy and the baby after it is born.

3.8 What happens if something goes wrong?

If you are injured because of your participation in this research study, you will receive any medical treatment that is necessary to assist your recovery from the injury.

Compensation will be provided by the Sponsor's insurance for any injury caused by taking part in this study in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI). Compensation will be paid where the injury probably resulted from –

- The study vaccine administered as part of the trial protocol,
- Any test or procedure you received as part of the trial.

The sponsor will not reimburse expenses that are attributable to the negligence, misconduct, error or omission of any person employed by or acting on behalf of the study doctor or study site, or that are attributable to your failure to follow instructions.

You do not give up any legal rights by signing this form.

If you experience an adverse reaction (any unusual symptoms) or injury, and if emergency medical treatment is required, you will report immediately to:

_____ <<Site to insert contact name and number>>

4. BENEFITS OF PARTICIPATION

Are there any benefits to taking part in this study?

This is the second study in human participants and the clinical benefits of VLA2001 have not yet been established. Although the vaccine might induce immune responses that may be protective, you might not experience any direct benefit from taking part in this study. The information obtained from this study may help prevent future participants from contracting COVID-19 and will provide important information about how well people respond to VLA2001.

5. ALTERNATIVES TO PARTICIPATION

5.1 Do I have any other choices?

As of mid-January 2021, 3 vaccines have been authorized for emergency use in Europe, United Kingdom, and the USA. Your doctor can discuss available alternatives and answer any questions you may have. Your doctor will discuss with you the risks and benefits of these alternative vaccines.

5.2 What happens if you get access to a nationally deployed vaccine or approved Covid-19 vaccine during your participation in the study?

It is possible that during the course of this study you will become eligible, through the national vaccination roll-out, to receive a nationally deployed or approved COVID-19 vaccine. You can discuss with your doctor and others to make an informed choice about whether you should take the approved COVID-19 vaccine or continue with the study. Given the status of the national roll-out, although adults aged 18 years or more are eligible to take part in this study, it is expected that the majority of participants in the randomly assigned part of the study will be aged between 30 and 50 years at the time of enrolment.

If you decide to receive a nationally deployed COVID-19 vaccine, you will be told by your study doctor which vaccine you have received during the study. The study doctor will also advise you on consequences and the necessity to complete the study visits according to the schedule of this study.

If you have already received the 2 doses of the study vaccine, you will be advised to wait until after Day 43 before receiving any additional nationally deployed vaccine.

If you decide to take a nationally deployed COVID-19 vaccine, you will be encouraged to still attend all remaining study visits and procedures. However, if you decide not to attend the remaining study visits, you will be asked to perform a visit similar to the regular visit performed at the end of the study.

6. PRIVACY AND CONFIDENTIALITY

6.1 Why is my personal data processed and how will it be kept confidential?

Processing of your personal data is required for the purpose of legitimate interest, which is to improve health provision and prevention and achieve scientific advances. The processing of your personal data is therefore necessary for scientific research purposes and shall be subject to appropriate safeguards for the rights and freedoms of data participants. The processing of your data is also necessary for compliance with legal obligations to which the Sponsor is subject and is necessary for reasons of public interest in public health, such as ensuring high standards of quality and safety of health care and of medicinal products or medical devices. Your personal information will be used for the purpose of this study, as well as for the purpose of future scientific research activities that are unanticipated but will be consistent with the general research purpose(s) for which the personal data were originally collected.

All reasonable efforts will be taken to keep all medical records and research materials that could identify you confidential. All data which are collected and obtained for the purpose of the study will only be stored, evaluated, and possibly forwarded in pseudonymised form. Pseudonymised means that neither your name nor initials will be documented, only a number and/or a letter code, possibly together with your year of birth. The code which is required to match the coded data with your name is accessible only to the study doctor and his/her study staff, monitors, and auditors, as required. If the results of this study are published in the medical literature, you will not be identified by name.

6.2 What information is being collected and what are my rights?

In addition to the usual medical records/files and basic personal information (such as name contact details, sex, height, weight), specific health data are recorded by the study doctor for this clinical study, as described in the previous sections. You have the right to request access to, correction of, or erasure of your health information, request restrictions on or object to the processing of your health information or the portability of your health information. If you would like to make any such requests, contact the Data Protection Officer listed below. The site's and/or Valneva Austria GmbHs' ability to comply with your requests will be limited by the requirements of the study, the policies of the site and Valneva Austria GmbH, and applicable laws and regulatory requirements. For more information about your rights related to your health information, you can contact the Site´s Data Protection Officer at <<insert a dedicated telephone number, and a dedicated e-mail address>>.

The Sponsor may not give you access to your data during the study, because disclosure of that information would jeopardise the integrity of the study. After the study is over, you can ask your study doctor for this information.

If at any time during this study you feel that you have not been informed enough about your privacy rights about your health information, or you feel that the privacy of your health information has not been protected, you may contact the above-mentioned Data Protection Officer.

If you are not happy with the Sponsor's response or believe the Sponsor processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

6.3 Who will have access to my data?

In addition to your study doctor and his/her staff who will have access to your personal data, Pharm-Olam staff, and vendors (for example database companies or central laboratories) will also have access to your coded data.

If you are registered on the NHS COVID 19 registry Valneva will provide information to NHS Digital of who has signed up to the study for the purpose of marking them inactive on the NHS COVID-19 registry so they will not be contacted about future studies. NHS Digital also note this in their Privacy Notice.

The coronavirus (COVID-19) pandemic may prevent Pharm-Olam representatives or other agents designated by the Sponsor, to visit the site and enable review of critical data in your medical records that refer to your eligibility, safety, and the main study endpoints.

Current guidance by research authorities allows for the following to take place during the COVID-19 pandemic:

- That your data generated for this study may be reviewed remotely
- That this remote monitoring will take place in a safe and secure manner
- That your data will be transferred outside of the UK and that the Sponsor will ensure all relevant safeguards, such as standard contractual clauses, are in place to protect your personal, coded data.

By signing this form, you understand that medical information about you obtained during this study may be made available to authorised representatives of other foreign health agencies (Regulatory Agencies) for the purpose of ensuring that the medical information was collected ethically and accurately as well as public authorities in response to lawful requests and law enforcement requirements. You also understand that this medical information may be made available to the Sponsor or persons acting on behalf of the Sponsor (including contractors) for the purpose of conducting the trial and analysing study results or study personnel who may be evaluating the results of this study.

6.4 Will my data be transferred to other countries?

You are aware that your coded data will be processed and used in IT systems and by vendors in other countries and will be transferred outside the UK to other countries where personal data protection laws may be less strict. However, appropriate safeguards will be implemented for data transfers, if required, such as agreements and other mechanisms issued by the data protection authorities. If you would like to learn more about this, you may contact the Site DPO.

A description of this clinical study will be available on the EMA Clinical Trial Register on https://www.clinicaltrialsregister.eu/ and other national or international web sites. These websites will not include information that can identify you. At most, the web sites will include a summary of the clinical study and its results. You can search these web sites at any time.

6.5 How long will my data be stored?

The data collected during this study will be stored for at least 15 years after completion or termination of the study or if required by law. After that, your personal data will be deleted if this does not contradict the legislative requirements for their storage.

Some of your samples will be tested and then destroyed while others (the so-called backup samples) will be shipped for long-term storage (15 years) to contracted partners of Valneva, who are located either in the UK and/or also in the European community and North America.

The Sponsor will destroy the samples after the data collected during this study have been analysed and submitted to relevant Competent Authorities (such as the Federal Agency for Medicines and Health Products) and no questions are expected by the respective Competent Authorities, or as required by local law.

If you withdraw your consent for participating in this study, your personal data collected before you withdrew your consent may still be used for the purpose of the study. After you have withdrawn your consent for participating in the study, no further data and samples will be collected from you for the purposes of this study unless you agree otherwise, for example, you agree to have further tests and examinations. If you do agree to have further data collected after you have withdrawn your consent, these study data may also be used for the purpose of the study.

If you stop participating in this study, you may ask that your samples may not be used by contacting the study doctor. If you ask for this, your samples will be destroyed once all protocol-defined procedures are completed. Valneva Austria GmbH and its authorised representatives (including contractors) may continue to use the samples collected during your participation in the study for tests and procedures described in this section.

6.6 What will happen to the results of the study?

The results of this study may be published in the scientific press. You will not be identified by these results.

6.7 Who has reviewed the study?

International guidelines exist to ensure clinical studies are performed properly and ethically. All studies are performed to these international standards. This study has been reviewed by a Research Ethics Committee (REC) as well as the appropriate Regulatory Authority and will be conducted to those standards.

7. CONSENT STATEMENT

	Please initial the boxes below to indicate your approval
I agree that my GP will be informed of my participation in this trial. I authorise the release of my medical records to the Sponsor, agents of the Sponsor and other governmental agencies.	
I agree to my GP sharing relevant medical information on adverse events with the study doctor while I am taking part in the study.	
I understand that I will receive and may keep a copy of this signed and dated consent form.	
I have not waived any of the legal rights that I would have, if I were not a participant in a research study.	
I understand that my personal, coded data will continue to be processed after the completion of the study or after I withdraw from the study if necessary, for reasons of public interest in public health, for archiving purposes in the public interest, for scientific research purposes, or for statistical purposes.	
I agree to have my samples saved for future testing.	
I agree that my personal, coded data will be transferred outside of the UK to other countries where personal data protection laws may be less strict for the purpose of conducting the study.	
I agree to participate in the study. I have thoroughly read, understood, and had full explanation of all the information in this consent form. I understand that I am free to not participate in this research study or to withdraw at any time.	
I consent for Valneva to provide information to NHS Digital of who has signed up to the study for the purpose of marking me inactive on the NHS COVID-19 registry so I will not be contacted about future studies.	

_____	_____	_____(24h)	_____
Printed Name of Participant	Date	Time	Signature of Participant

STATEMENT OF PERSON OBTAINING CONSENT

I, the undersigned, certify that to the best of my knowledge the participant signing this consent form had the study fully and carefully explained and clearly understands the nature, risks, and benefits in his/her participation in this research study.

_____	_____	_____(24h)	_____
Printed Name of Person Obtaining Consent	Date	Time	Signature of Person Obtaining Consent