INFORMATION SHEET AND CONSENT FORM

Study Title:	A Randomized, Observer-blind, Controlled, Superiority Study to Compare the Immunogenicity against COVID-19, of VLA2001 Vaccine to AZD1222 Vaccine, in Adults Including a Randomized, Observer-blind, Placebo Controlled Part in Adolescents (≥ 12 to <18 years)
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 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.

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 the sponsor of this study. 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?

A research study is something like a science project in school. The purpose of this study is to see if the VLA2001 vaccine is safe for use and to see if it helps people develop immunity against COVID-19 disease. Investigational means that VLA2001 has not been approved for use. VLA2001 will be compared to a placebo, a substance that has no therapeutic effect and is used as a control in the testing of new drugs.

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 a laboratory and prepared in a way that makes them lose their disease-producing capacity but allows 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.

The vaccine will be injected into a muscle in your arm. Although COVID-19 vaccines have been offered in the national roll-out 12 weeks apart in order to immunise as many people as quickly as possible, studies have shown that high levels of protection are provided after a shorter dose interval like the one which will be used in this study.

If you are assigned to the VLA2001 group, your first dose of VLA2001 will be on Day 1 of the study and the second dose will be on Day 29. You will receive a third dose (booster vaccination) on Day 208 (Month 7).

If you are assigned to the placebo group, your first dose of a placebo will be on Day 1 of the study and the second dose will be on Day 29. You will receive your first dose of VLA2001 on Day 208 (Month 7), the second dose on Day 236 (Month 8).

1.3 How many people will take part in this study?

This study already enrolled more than 4000 adult participants with approximately 3000 receiving VLA2001 and 1000 receiving a comparator vaccine. At this stage, the study is extended to enroll approximately 660 people who are 12 to 17 years old. All of the study doctor's sites are in the UK.

1.4 How long will I be participating in this study?

You will take part in this study for up to 14 months. There will be a total of 8 to 10 visits depending on which group you are assigned. 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?

Whether you will receive VLA2001 or placebo is decided randomly, like flipping a coin. You will have a 1 in 2 chance of receiving VLA2001 and a 1 in 2 chance of receiving placebo.

1.6 Will I know which study vaccine I am receiving?

Until Day 236 (Month 8), neither you nor your study doctor will know which drug you were given. This information can be found if there is an emergency.

1.7 Can I stop participating in the study?

You are free to stop participating in this study at any time and without losing any medical benefits. 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 vaccine.

If you want to stop participating in the study, please tell the study doctor. He or She can tell you about stopping all or some 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 if the study ends before you have received all study vaccinations, you will not receive these 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 you have stopped 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 to the study doctor's office for clinical visits.

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 of 38.0°C or higher or 100.4°F or higher), 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 (tiredness),

- Muscle aches,
- Body aches,
- Headache,
- New loss of taste,
- New loss of smell,
- Nasal congestion,
- Runny nose,
- Nausea,
- Vomiting, and/or
- Diarrhoea (loose stools).

If you have confirmed COVID-19 symptoms, you will be tested at the study doctor's office 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 at the study doctor's office 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 to the doctor's office to have 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.

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	7 or 9 times (depending on whether you are randomly assigned to receive placebo)
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, you will be asked some questions to see if you are eligible and some tests will be done. 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 the planned procedures below:

Planned Procedures

Test/Procedure	Screening (Visit V0a)	Baseline (Visit V1a)	Schedule Study Visits
			Visits V2a, V3a, V4a, V5a, V6a, V7a, V8a, V9a and V10a
Physical examination	1 time	0	0
Symptom-driven physical examination (done only if there is a sign that you may be sick)	0	1 time	Up to 1 time per visit
Vital signs (blood pressure, pulse [how many times your heart beats per minute], and temperature)	1 time	1 time	3 times (Visits V2a, V5a and V6a)
Blood draws to check your current health (safety lab)	1 time	0	0
Pregnancy test (if you female and are able to have children)	0	1 time	2-3 times (Visits V2a, V5a and V6a as applicable)
Receive vaccination (3 times for VLA participants and 4 times for Placebo participants)	0	1 time	2-3 times (V2a, V5a and V6a as applicable)
Complete electronic diary 7 days after each vaccination (3 times for VLA participants and 4 times for Placebo participants)	0	1 time	2-3 times (V2a, V5a and V6a as applicable)
Prick test to check the presence of COVID-19 antibodies (an antibody is a protein produced by the body's immune system when it detects harmful substances)	1 time	0	0
Swab collection from the nostril to check if an active COVID-19 infection is present	0	1 time	0
Blood draws to check your immune response (the production of antibodies)	0	1 time	9 times (once at Visits V2a through V10a)
Blood draws to check the selectivity of your immune response (PBMC)* *only for 100 selected participants	0	1 time	5 times (once at Visits V3a, V5a, V6a, V7a, V9a and V10a)
Assessment of side effects	0	1 time	9 times (once at Visits V2a through V10a)
Recording medications	1 time	1 time	9 times (once at Visits V2a through V10a)

The screening visit and the baseline visit might be conducted on the same day.

Baseline blood (about 30.0 mL (2 tablespoons) for safety tests) and urine samples will be collected at Visit 0 (Screening visit) for standard clinical chemistry, haematology, blood clotting, and urinalysis. More blood may be collected if additional follow-up is needed for safety purposes.

These blood samples will be used to monitor your health and safety as well as the effects of VLA2001.

You will 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 if you have 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 (if there is redness or swelling) where you received the vaccination. 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.

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

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 to be used in 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 up to 15 years after the end of the 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.

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.

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 compensation listed below for taking part in this research study. You will be compensated £50 per visit as indicated in the table below for time and travel up to £430 (if you are in the VLA2001 group) or up to £540 (if you are in the

placebo group). Compensation for eDiary completion can only be granted if the diary was completed according to the instructions. You will receive compensation for the visits that you finish.

The schedule of payments will be discussed with you during the Screening 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.

The compensation you will receive will be as follows:

Study Payment Schedule	**VLA2001**	**Placebo**
Visit 0a/Screening	£50	£50
Visit 1a/Day 1 (Vaccination 1)	£50	£50
Vaccination 1 - 100% eDiary completion	£10	£10
Visit 2a/Day 29 (Vaccination 2)	£50	£50
Vaccination 2 - 100% eDiary completion	£10	£10
Visit 3a/Day 43 (Month 1.5)	£50	£50
Visit 4a/Day 71 (± Month 2.5)	£50	£50
Visit 5a/Day 208 (Month 7) (Vaccination 3)	£50	£50
Vaccination 3 - 100% eDiary completion	£10	£10
Visit 6a/Day 236 (Month 8) (Vaccination 4 if applicable)	£50	£50
Vaccination 4 - 100% eDiary completion	N/A	£10
Visit 7a/Day 250 (± Month 8.5)	N/A	£50
Visit 8a/Day 278 (± Month 9)	N/A	£50
Visit 9a/Month 12	£50	N/A
Visit 10a/Month 14	N/A	£50
Total:	**£430**	**£540**
Early Termination Visit	£50	£50
Unscheduled Visit (e.g. COVID-19 illness related, rescreening)	£50	£50
Screening Failure	£50	£50

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 or 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 or not 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.

3.2 What are the likely risks with VLA2001?

To date approximately 3,150 adults have received at least one dose of VLA2001 vaccine in two ongoing trials. An independent group of experts is regularly reviewing the safety information and to date has not identified any safety concern.

Overall, the study showed that VLA2001 is safe and well-tolerated at all dose levels tested. A description of the most frequent side effects is given below (effects observed in at least 1 of 10 study participants) who were observed following vaccination and how common they were. 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 (injection) site tenderness (pain upon touching).

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

- Vaccination (injection) site pain,
- Headache,
- Tiredness,
- Muscle Pain

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

- Nausea/vomiting

Most events were 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 similar.

3.3 What are the risks of using VLA2001 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. Because the side effects of using VLA2001 in combination with other drugs are currently unknown, please discuss any concerns you may have with the study doctor.

Other Side Effects:

As with all research studies, the vaccines and procedures in this study 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 a person 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), and/or
- 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.

3.4 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.

3.5 Could VLA2001 or Placebo be harmful to an unborn or breastfed baby?

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

Female Participants:

Although risks of injury to an unborn child are currently unknown, 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 currently unknown. 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 have not had surgery to remove your uterus, both ovaries, or both fallopian tubes) and are sexually active, 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 and up to 3 months after the last dose of vaccine.

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

Highly Effective Methods of Birth Control include:

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

If you are not sexually active or 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.

3.6 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/babies after birth.

Please be assured that any pregnancies will be managed sensitively and according to national guidelines. There are processes in place to ensure above all, your safety and well-being.

3.7 What happens if something goes wrong?

Payment for any harm caused by this study is in line with the guidelines of the Association of the British Pharmaceutical Industry (ABPI). Payment will be made by the Sponsor's insurance when the injury probably resulted from your receiving an experimental vaccine at the time your baby/babies were conceived.

The Sponsor will not pay expenses that are caused by the carelessness, mismanagement, error, or omission of any person employed by or acting on behalf of the study doctor or study site, or that are caused by you/your partner's failure to follow instructions.

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

You can contact the study doctor for more information on payment in this clinical trial.

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 result in 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-July 2021, 1 vaccine for adolescents has been authorized for use in the United Kingdom. Your doctor can discuss available alternatives and answer any questions you may have. Your doctor will discuss with you the risks and benefits of this alternative vaccine.

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 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.

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 follow all study procedures. However, if you decide not to attend the remaining study visits, you will be asked to have a visit like the regular visit 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?

Your personal information will be used for this study as well as for future scientific research activities that are unknown at this time but will be consistent with the general research purpose(s) for which the personal data were originally collected.

All efforts will be taken to keep confidential all medical records and research materials that could identify you. All data collected and obtained for the purpose of the study will only be stored, evaluated, and possibly forwarded including only a number and/or a letter code, possibly together with your year of birth. Only your study doctor, people who check the data, and other auditors will have access to this code.

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), other health information is collected 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 deletion of your health information. You can also ask for restrictions on, or object to how your health information will be used or the transfer of your health information. If you would like to make any such requests, please contact the Data Protection Officer given 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, as well as 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 if you feel that the privacy of your health information has not been protected, you may contact the above-mentioned Data Protection Officer (DPO). You also have a right to lodge a complaint with your country's supervisory data protection authority.

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.

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.

Since local regulations and site procedures have allowed for remote review of certain data held in your medical records with the aim of ensuring the integrity of study data, patient safety and study continuity, Pharm-Olam or other agents designated by the Sponsor may access these data remotely by:

- Having the site upload your medical records, scans or files to a shared location not provided by the site. In this case, the contract research Organization (CRO) will take all appropriate measures to protect your information, such as deleting or obscuring any information showing your identification before providing the records or files to the Clinical Research Associate (CRA), ensuring the documents are deleted as soon as the remote review is completed. Doing this will not involve any data transfers outside your home country and the European Union, will ensure all relevant safeguards are in place, such as standard contractual clauses.

The Sponsor will ensure that any individual accessing the data in your medical record maintains its security and confidentiality and does not process the data for any other purpose than the remote review of critical data in your medical records that refer to your eligibility, safety, and the main study endpoints.

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 to 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?

Your coded data will be used in computer systems and by companies in other countries and will be transferred outside the UK to other countries where personal data protection laws may be less strict. However, appropriate protection will be used for data transfers. 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 European Medicines Agency (EMA) Clinical Trial Register at https://www.clinicaltrialsregister.eu/ and other national or international websites. These websites will not include information that can identify you. At most, the websites will include a summary of the clinical study and its results. You can search these websites at any time.

6.5 How long will my data be stored?

The data collected during this study will be stored for up to 15 years after completion or discontinuation 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.

Your samples will be tested and then destroyed. Backup samples will be shipped for long-term storage in the UK for a period of approximately 12 months after end of the study and may be stored thereafter at Valneva.

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, if 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 should not be used by contacting the study doctor. If you ask for this, your samples will be destroyed once all 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

Participant Number: 2001-2-_ _-_ _ _

Please initial the boxes below to indicate you have read this form

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 up to 15 years after the end of the study for potential 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.	

_____	_____	_____(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