INFORMATION SHEET FOR PARENT/GUARDIAN OF PARTICIPANTS AGED 12 - 15 YEARS OLD

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

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This form gives you important information about this study to help you decide whether you want your child to participate or not. It describes the purpose of this study, the study procedures, the possible risks and provides information about 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 child's participation in this study is voluntary. You are free to say yes or no. If you do not want them to participate, their regular medical care and legal rights will not be affected. They 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?

The purpose of this study is to evaluate whether the investigational VLA2001 vaccine is safe to use and to measure the immune response induced by this vaccine candidate against COVID-19. Investigational means that VLA2001 has not been approved by Regulatory Authorities 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 administered 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 child is assigned to the VLA2001 group, their first dose of VLA2001 will be on Day 1 of the study and the second dose will be on Day 29. They will receive a third dose (booster vaccination) on Day 208.

If they are assigned to the placebo group, their first dose of a placebo will be on Day 1 of the study and the second dose will be on Day 29. They will receive their first dose of VLA2001 on Day 71 (Month 2.5) and the second dose on Day 99 (Month 3.5).

1.3 How many people will take part in this study?

At least 660 people who are 12 to 17 years old will participate. All of the study doctor's sites are in the UK.

1.4 How long will my child be participating in this study?

Your child will take part in this study for up to 14 months. There will be a total of 8 or 9 visits depending on which group they are assigned. There may be additional appointments that they will need to attend if they develop any symptoms which may indicate they have a COVID-19 infection.

1.5 What are the chances that my child will get VLA2001?

Whether they will receive VLA2001 or placebo is decided randomly, like flipping a coin. They 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 drug my child is receiving?

Until Day 71, neither you, your child, nor the study doctor will know which drug your child is given. In an emergency, the study doctor can find out what study drug your child has received. At the Day 71 (Month 2.5) visit all adolescent participants will know what treatment they were assigned.

1.7 Can my child stop participating in the study?

Children are free to stop participating in this study at any time, and they will not lose any medical benefits. All information and samples collected from them before they stop the study may still be used by Valneva Austria GmbH to understand more about the study vaccine.

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

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

- Staying in the study could be harmful to them or
- They are not able to complete the study procedures as required.

The study is stopped by Valneva Austria GmbH for reasons not related to them.

There may be other reasons to stop their participation in this study that are not known at this time. If they stop participating in the study or if the study ends before they have received all study vaccinations, they will not receive these and they may be asked to come back for final tests and procedures.

If they stop participating in the study, any personal data collected before they 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 child's 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 MY CHILD PARTICIPATES IN THE STUDY

2.1 What is my child expected to do if they take part?

If you and your child agree for them to take part in this research study, you will both be asked to sign a Research Ethics Committee (REC) approved informed assent form and they must meet specific entry criteria for the study. While participating in this study, they must return to the study doctor's office for clinical visits.

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

Immediately: You should contact the study site immediately in case they 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 they 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 they have confirmed COVID-19 symptoms, they will be tested at the study doctor's office to check if they have a COVID-19 infection or not (PCR test).

If the test is negative, they will have a second PCR test at the study doctor's office after 2 days. If the result is still negative, they will continue with the scheduled visits as planned.

If either test is positive, they 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 their immune response will be taken. Standard, approved infection control procedures will be followed at all times.

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

They 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	8 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 they decide to participate in the study, they will be asked some questions to see if they are eligible and some tests will be done. If the test results show that they meet the study requirements, then they will be able to start receiving the study drug. If the test results show that they do not meet the study requirements, they will not be able to start receiving the study vaccine.

As part of their participation in this study, they will have tests or procedures at each visit as shown in the Planned Procedures below:

Planned Procedures

Test/Procedure	Screening (Visit V0a)	Baseline & blinded treatment (Visits V1a, V2a, V3a)	Schedule Study Visits	
			Placebo group (Visits V4p, V5p, V6p, V7p and V8p)	VLA2001 group (Visits V4ab, V5ab, V6ab, V7ab)
Physical examination	1 time	0	0	0
Symptom-driven physical examination (done only if there is a sign that they may be sick)	0	Up to 1 time	Up to 1 time per visit	Up to 1 time per visit
Vital signs (blood pressure, pulse [how many times your heart beats per minute], and temperature) *To be measured before and after vaccination at each visit*	1 time	4 times (Visits V1a and V2a)	4 times (Visits V4p and V5p)	2 times (Visit V5ab)
Blood draws to check their current health (safety lab)	1 time	0	0	0
Pregnancy test (if female and are able to have children)	0	2 times (Visits V1a and V2a)	2 times (Visits V4p and V5p)	1 time (Visit 5ab)
Receive vaccination (3 times for VLA participants and 4 times for Placebo participants)	0	2 times (Visits V1a and V2a)	2 times (Visits V4p and V5p)	1 time (Visit 5ab)
Complete electronic diary 7 days after each vaccination (3 times for VLA participants and 4 times for Placebo participants)	0	2 times (Visits V1a and V2a)	2 times (Visits V4p and V5p)	1 time (Visit 5ab)
Prick test to check the presence of COVID-19 antibodies (an antibody is a protein produced by the body's immune system in response to the presence of a foreign substance)	1 time	0	0	0
Swab collection from the nostril to check if an active COVID-19 infection is present	0	1 time	0	0
Blood draws to check the immune response (the production of antibodies)	0	3 times	4 times (Visits V4p, V5p, V6p and V8p)	4 times (Visits V4ab, V5ab, V6ab and V7ab)
Blood draws to check the selectivity of the immune response (PBMC)* *only for 100 selected participants	0	2 times (Visits V1a and V3a)	4times (Visits V4p, V5p, V6p, and V8p)	4 times (Visits V4ab, V5ab, V6ab and V7ab
Assessment of side effects (throughout the study)	0	3 times	5 times (Visits V4p through V8p)	4 times (Visits V4ab through V7ab)
Recording medications	1 time	3 times	5 times (Visits V4p through V8p)	4 times (Visits V4ab through V7ab)

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 their health and safety as well as the effects of VLA2001.

You will be asked to help your child complete an eDiary (an electronic app used on your mobile phone) where you enter details related to any side effects your child may experience after vaccination or if they have COVID-19 symptoms. Your child will answer questions about how they are feeling. This will be completed by your child at home for 7 days after each vaccination. Some of the questions will ask you to enter your child's daily oral temperature and to measure the size of the area (if there is redness or swelling) where they received the vaccination. The study team will help you to download, install and become familiar with the app. They will provide you with a measuring ruler to measure any reactions at the injection site and an oral thermometer.

If study participants contract COVID-19, they 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 them to check their health and immune response; a nasal swab and saliva sample will also be collected. They will be asked about their medications and how they 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 them to come back for additional safety tests after the end of the study.

2.3 What will happen to samples taken from my child?

In addition to the research you and your child are consenting to under this research study, Valneva Austria GmbH would like to store their 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 up to 15 years after the end of the study for potential future testing. If you agree to permit their samples to be analysed in the future, the results will not be provided to you or your child.

Your child will not benefit directly from the research on their samples. The benefits of research using their 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. Neither you or your child will 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 child's name or medical records. These samples cannot be linked back to your child by the testing laboratory.

Valneva Austria GmbH will not use their blood for any other tests without permission. No one other than the Sponsor (and/or people or companies that the Sponsor works with) will test their samples. All their samples will be labelled with a special code. Only the study doctor and his/her

study staff will be able to link their samples to them. All information obtained from their samples will be kept confidential, as stated in the privacy and confidentiality section of this form.

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

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

If they are selected for participation, they may receive the compensation listed below for taking part in this research study. They will receive vouchers up to £170 (if they are in the VLA2001 group) or up to £200 (if they are in the placebo group). Compensation for eDiary completion can only be granted if the diary was completed according to the instructions. They will receive compensation for the visits they finish.

You will be compensated £50 per visit as indicated in the table below for time and travel up to £400 (if your child is in the VLA2001 group) or up to £450 (if your child is in the placebo group). In addition, you will receive compensation for each unscheduled visit (e.g., COVID-19 illness-related visit or rescreening). You will receive compensation for the visits they finish.

If they do not meet the criteria for the study at the screening visit and are not able to take part in the study, you and they will be compensated only for that visit.

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

Study Payment Schedule	**VLA2001**	**Placebo**
Visit 0a/Screening	£20 voucher/£50	£20 voucher/£50
Visit 1a/Day 1 (**Vaccination 1**)	£20 voucher/£50	£20 voucher/£50
Vaccination 1 - 100% eDiary completion	£10 voucher	£10 voucher
Visit 2a/Day 29 (**Vaccination 2**)	£20 voucher/£50	£20 voucher/£50
Vaccination 2 - 100% eDiary completion	£10 voucher	£10 voucher
Visit 3a/Day 43 (Month 1.5)	£15 voucher/£50	£15 voucher/£50
Placebo Group		
Visit 4p /Day 71 (Month 2.5) (**Vaccination 3**)	N/A	£20 voucher/£50
Vaccination 3 - 100% eDiary completion	N/A	£10 voucher
Visit 5p/Day 99 (Month 3.5) (**Vaccination 4**)	N/A	£20 voucher/£50
Vaccination 4 - 100% eDiary completion	N/A	£10 voucher
Visit 6p (Month 4)	N/A	£15 voucher/£50
Visit 7p (Month 10.5)	N/A	£15 voucher/£50
Visit 8p (Month 12)	N/A	£15 voucher/£50
VLA2001 Group		
Visit 4ab/Day 71 (Month 2.5)	£15 voucher/£50	N/A
Visit 5ab/Day 208 (Month 7) (**Vaccination 3**)	£20 voucher/£50	N/A
Vaccination 3 - 100% eDiary completion	£10 voucher	N/A
Visit 6ab/Day 222 (Month 7.5)	£15 voucher/£50	N/A

Study Payment Schedule	VLA2001	Placebo
Visit 7ab (Month 12)	£15 voucher/£50	N/A
Total:	**£170 voucher/£400**	**£200 voucher/£450**
Early Termination Visit	£15 voucher/£50	£15 voucher/£50
Unscheduled Visit (e.g. COVID-19 illness related, rescreening)	£15 voucher/£50	£15 voucher/£50
Screening Failure	£20 voucher/£50	£20 voucher/£50

2.5 What if new information becomes available?

You and your child will be informed of any new findings related to the vaccine they are taking during this study. These findings may affect your child or your willingness for them 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 child's well-being and safety will be thoroughly monitored throughout the study. Please, tell the study doctor or study staff right away if they have any side effects. Please tell them if they have any other problems with their health or the way they 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 clinical 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 was 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, and
- 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 your child is taking, have taken recently, or are planning to take, including herbal medicines, supplements and drugs they take without a prescription. Because the side effects of using VLA2001 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 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. Your child 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 them 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 your child has any of these symptoms during the study.

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

Blood Samples:

Your child will have their 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 their blood taken may also cause them to feel sick and/or lightheaded.

Nasal Swab Sample:

They may feel discomfort when the swab is inserted into their nose. They may flinch, have watery eyes, or cough. They 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 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 your child becomes 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 your child could become pregnant (that is, they have not had surgery to remove their uterus, both ovaries, or both fallopian tubes), and they are sexually active they should let their sexual partner know they are in this study and they should use acceptable methods of effective birth control during the study and up to 3 months after the last dose of vaccine.

Your child must have a negative pregnancy test prior to enrolment if they are able to have children and are sexually active.

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

Male Participants:

If your child is a sexually active male, they 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 they use condoms starting with the first dose of study vaccine until 3 months after he receives his last dose.

3.6 What if my child or their partner becomes pregnant during the study?

Female Participants:

If your child becomes pregnant or thinks they 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 them, and ask them for information on the pregnancy and the baby/babies after birth.

Please note: In the event of pregnancy in girls under the age of 16, any safeguarding issues may be reported to the relevant authorities.

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 child/their partner receiving an experimental vaccine at the time their 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 your child/their partner's failure to follow instructions.

Your child does not give up any legal rights by providing assent.

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 should 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, your child 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. The doctor can discuss available alternatives and answer any questions you or your child may have. Your doctor will discuss with you the risks and benefits of this alternative vaccine.

5.2 What happens if my child gets access to a nationally deployed vaccine or approved Covid-19 vaccine during their participation in the study?

It is possible that during this study your child will become eligible, through the national vaccination roll-out, to receive a nationally deployed or approved COVID-19 vaccine. You can discuss with the doctor and others to make an informed choice about whether your child should take the approved COVID-19 vaccine or continue with the study.

If you decide for them to receive a nationally deployed COVID-19 vaccine, they will be told by their study doctor which vaccine they 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 they have already received the 2 doses of the study vaccine, they will be advised to wait until after Day 43 before receiving any additional nationally deployed vaccine.

If you decide for them to take a nationally deployed COVID-19 vaccine, they will be encouraged to still attend all remaining study visits and follow all study procedures. However, if you or they decide not to attend the remaining study visits, they 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 child's personal data processed and how will it be kept confidential?

Your child's 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 your child. 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 their year of birth. Only the 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 child's 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 child's health information. You can also ask for restrictions on or object to how your child's health information will be used or the transfer of their 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 child's rights related to their health information, they can contact the Data Protection Officer at <<insert a dedicated telephone number, and a dedicated e-mail address>>.

The Sponsor may not give you access to your child's 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 child's privacy rights about their health information or if you feel that the privacy of your child's 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 child's data?

In addition to the study doctor and his/her staff who will have access to your child's personal data, Pharm-Olam staff and vendors (for example database companies or central laboratories) will also have access to their 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 child's medical records that refer to their eligibility, safety and the main study endpoints.

Since local regulations and site procedures have allowed for remote review of certain data held in your child's 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 child's 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 their information, such as deleting or obscuring any information showing their 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 child's 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 their medical records that refer to their eligibility, safety, and the main study endpoints.

By signing the assent form, you understand that medical information about your child 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, to the ethics committee (groups that review study safety and ethics and to ensure participants' rights are not violated) or to study personnel who may be evaluating the results of this study.

6.4 Will my child's data be transferred to other countries?

Your child's 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 your child. 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 child's 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 child's personal data will be deleted if this does not contradict the legislative requirements for their storage.

Your child's samples will be tested and then destroyed, but 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 or your child withdraw consent for participating in this study, their personal data collected before withdrawal of consent may still be used for the purpose of the study. After consent withdrawal for participating in the study, no further data and samples will be collected from them for the purposes of this study unless they and you agree otherwise, for example, if you and they agree to have further tests and examinations. If you and your child do agree to have further data collected after they have withdrawn their consent, these study data may also be used for the purpose of the study.

If they stop participating in this study, you or your child may ask that their samples not be used by contacting the study doctor and 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. Your child 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.