PARENT INFORMATION SHEET AND CONSENT FORM – UK

STUDY TITLE:	A Phase 2b, Multi-Center, Placebo-Controlled, Randomized Study of BPZE1 Intranasal Pertussis Vaccine in Healthy School-Age Children to Assess the Immunological Response and Safety Profile of a Single Dose BPZE1 With and Without Co-Administration of Tetanus, Diphtheria, and Acellular Pertussis (Boostrix™)
SHORT TITLE:	Phase 2b trial of BPZE1 Nasal Spray Vaccine in Healthy Children
PROTOCOL NUMBER:	IB-201P
SPONSOR:	ILiAD Biotechnologies
STUDY DOCTOR:	Dr Jolanta Bernatoniene University Hospitals Bristol and Weston NHS Foundation Trust, Bristol Vaccine Centre Upper Maudlin Street, Bristol, BS2 8AE Office Hours Tel: 0117 342 0174 Out of Hours Tel: 07769 960 542
ETHICS COMMITTEE:	Fast Track

If you are a parent, guardian of the participant, your signature is required on this form before your child who is under the age of 16 can participate in the study.

Children aged 6 to 11 and those 12-15 years of age will be given separate assent forms to confirm their willingness to participate. If a child is capable of giving assent, he or she may choose not to participate even if the parent(s) gives consent.

Invitation

We are asking you to consider whether you would like your child to participate in a research study. This document explains the details of this research study and your child's possible role as a participant, so that you can make an informed decision whether you would agree to this participation or not. Please read this document with care, if you have questions about the study or what will happen in the study, please ask your child's study doctor or a member of the study team. If you have a question later that you did not think of now, you can call your child's study doctor or a member of the study team or ask them during your next visit. You may take a copy of this sheet with you. You can take your time to read this sheet and may also want to take this home and discuss it with others (family

members) before you decide. If you decide for your child to take part, you will be asked to sign this form (the informed consent form - ICF) either in wet ink or electronically. If you sign this ICF electronically it will be done via an Oxus Technologies Limited online Web Portal. To enrol you are required to provide your child's first name, last name, and email address. This information is held securely in the Oxus Technologies Limited system and will not be shared. Further information about how Oxus Technologies Limited manages your child's data is available here: https://oxustech.com/st-screener-consent/. You will receive a copy of the signed and dated form.

What is the purpose of this clinical research study?

We are asking for your child to join this study, to find out if a new nasal spray vaccine called BPZE1 can help prevent people from getting whooping cough (pertussis) or spreading it to others.

Approximately 600 school-age children and teenagers will take part in this study. This study will be done in approximately 25 locations in the United Kingdom, the United States (US) and/or other European/Commonwealth countries.

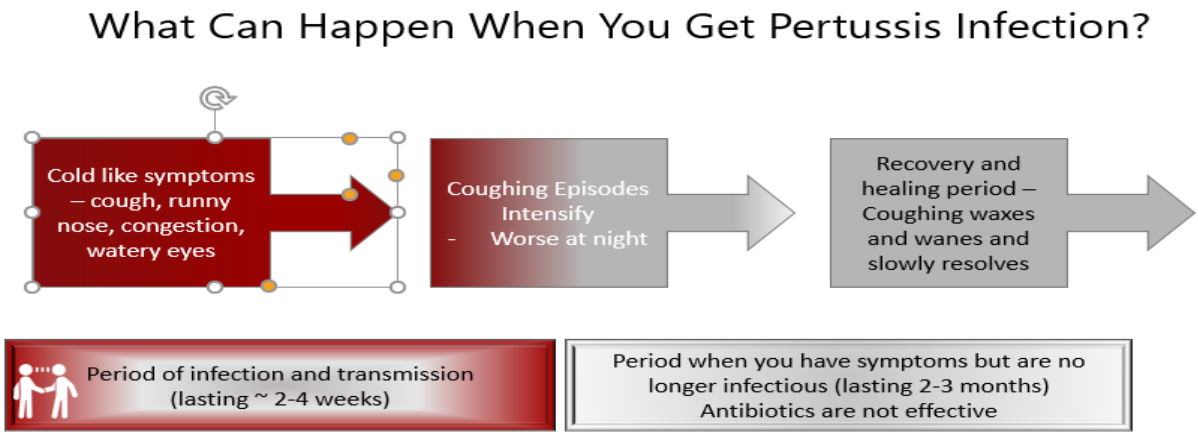
Since this is the first time BPZE1 is being given to school-age children and teenagers, additional safety measures are being taken. The first 45 children who sign up to participate in this study will be older children from 11 to 17 years of age. They will be vaccinated and followed-up for 7 days, their health will be assessed before others enrol.

What is the drug/device that is being tested?

Bordetella pertussis is a bacteria (germ) that causes infection in the upper airway and the lungs, often known as "whooping cough". This is a serious infection that is easily passed to others (it is very contagious). The effects of this infection can last up to 100 days. Although whooping cough is most dangerous in very young babies, it is now known that a lot of whooping cough disease is carried and transmitted by school age children, teenagers and young adults. Although we have vaccines against whooping cough, they are not as effective as we would like in preventing your child getting infected and transmitting the whooping cough bacteria to others. The current vaccine being used in the national immunization program is called Boostrix, and it works to protect you from severe disease but not from getting infected or passing the germ to others. Your child would have received Boostrix (or a similar vaccine) when they were younger. Whooping cough vaccines are given starting in infancy and then periodically during childhood, pregnancy and in adulthood.

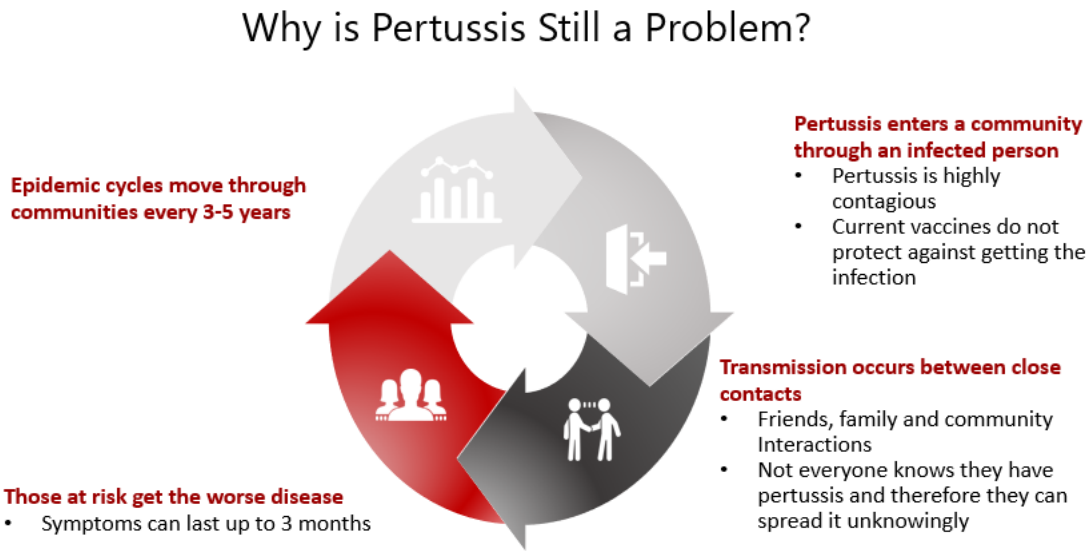
The study will test the BPZE1 pertussis vaccine which is given as a fine spray into the nose using a device called a mucosal atomization device, the study team can show you and your child this device. It is similar to using a nasal spray.

BPZE1 is an experimental vaccine, which means health authorities have not approved it to be used for prevention and spread of pertussis in adults and school-age children. This vaccine belongs to a group of vaccines known as live attenuated vaccines. Live attenuated vaccines use a weakened (e.g. attenuated) form of the germ (bacteria) that cannot cause the disease but can protect you because you make antibodies against the germ. Antibodies are the natural way your body fights infection from many germs. BPZE1 has been studied in 4 adult studies (over 350 adults have received this product) and this is the first study in school-age children. In these adult studies the vaccine has been well tolerated, without any serious side effects, and induced immunity against pertussis both in the nose and in the blood. The potential to protect against both pertussis transmission and disease could provide additional benefit to current pertussis vaccines used in your country.



We all make antibodies as a way of fighting infections. Current pertussis vaccines work by producing antibodies in the blood to protect you from getting really ill. However, they do not stop the infection from occurring nor can they control you getting the infection from someone else. BPZE1 works through an additional action – not only to induce antibodies in blood, but also to induce antibodies in the nose and throat. This should stop the bacteria from causing an infection in the first place and to stop the germ from being passed between people. Therefore, BPZE1 is being developed as a vaccine to help stop the spread pertussis as well as protect against getting ill. That is the reason for this study – to further understand how BPZE1 can protect children better against pertussis (whooping cough).

The BPZE1 vaccine contains modified *Bordetella pertussis* bacteria so that the bacteria cannot cause whooping cough (infection), but it can induce antibody responses to protect against *Bordetella pertussis* infection. BPZE1 is given in the nose as that is the natural way the *Bordetella pertussis* bacteria is passed around. The existing Boostrix vaccine is being used as a control vaccine in this study to compare to the effects of BPZE1. Boostrix protects you against tetanus, diphtheria and pertussis. It contains 3 proteins (pieces) of the pertussis germ known to be involved in whooping cough disease. An immune response can be induced against these 3 specific proteins only in the blood. The purpose of this study is to look at antibodies the body makes when your child is vaccinated with either BPZE1 or Boostrix™ or both vaccines.



To not reveal which vaccine(s) your child received, your child may be given an injection or an intranasal spray which does not contain the vaccine (which we call a placebo). A placebo looks like BPZE1 **or** Boostrix but will not have the active vaccine substance. Researchers use a placebo to help assess if a vaccine works and is safe, and there is no bias in the study because people (including the study doctors) do not know which vaccination someone receives. Only specific study staff members who prepare the injections will know to which group you are assigned.

For this reason, **from this point on, any references to the word "study vaccine" can mean BPZE1, Boostrix, or one of the placebos.**

Does your child have to take part?

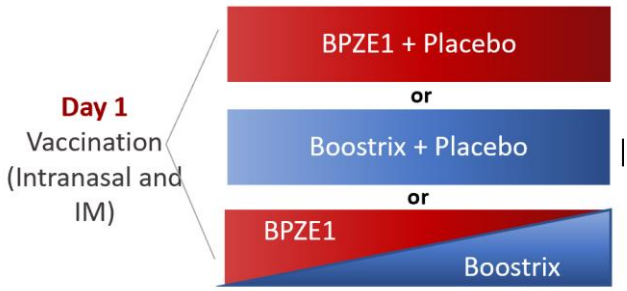
No. It is up to you to decide. Your child's participation in this study is voluntary and you can withdraw them from the study at any time. Doing so will not change your child's health care or their rights. If you do not want your child to join the study, you can talk to the study doctor about your child's health care. Your child's participation in this study may also be

stopped at any time for any reason by the study doctor or the sponsor without your agreement. Your signature may be taken electronically where appropriate.

What procedures are involved?

If you agree to your child's participation in this study, your child's study doctor will first check your child's eligibility for participation. Your child can qualify to be entered into the study and receive vaccination on the same day or you may need/want to return for the vaccination on another day.

Your child will be randomly assigned into 1 of 3 different study treatment groups to receive the BPZE1 vaccine, the Boostrix vaccine, or both. This means a computer program will randomly assign your child to be in one of these groups by chance; similar to tossing a coin.



The BPZE1 vaccine will be given using an atomization device (a small, cone-shaped device that attaches to a syringe and sprays the vaccine into the nose), which will spray a mist of the liquid vaccine into both nostrils. Your child will be asked to be partially reclined or sitting upright with your head and neck tilted back for a short time after this vaccine is given. Your child will receive the intranasal vaccination first and wait at least 10 minutes before receiving the next vaccination. If your child is one of the first 45 participants in the study, they will wait at least 30 minutes after the intranasal vaccination before receiving the intramuscular vaccination and again need to wait 30 min after the last vaccination before exiting the study site.

The Boostrix vaccine will be injected into your child's upper arm using a standard size needle and syringe that are usually used for vaccination. Your child will stay in the clinic for at least 30 minutes after this last vaccination to be monitored for any safety concerns.

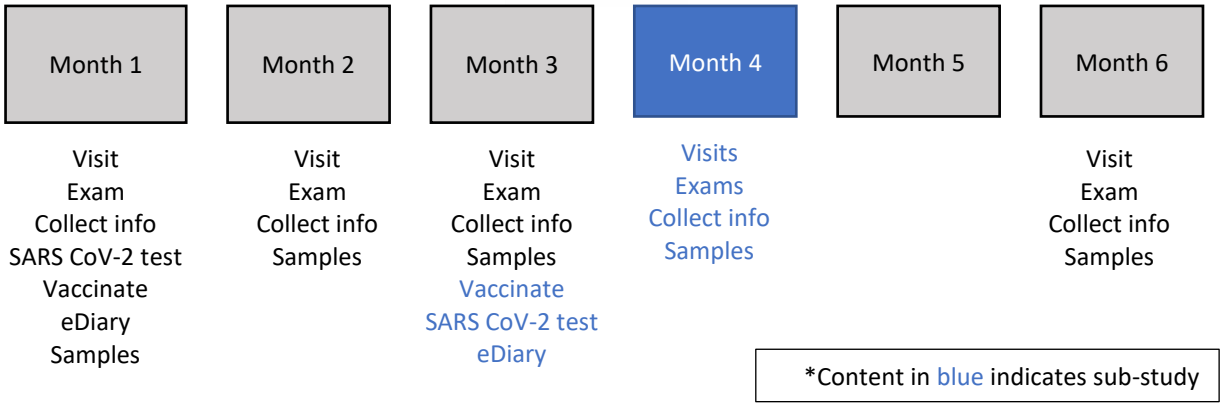
If your child is one of the first 45 participants in the study, they will also provide 1 teaspoon (approximately 5 ml) more blood for extra immunity testing and have a study visit 1 week after the vaccination day to assess any reaction to the vaccine and any ongoing health concerns. At this time, a nasal swab and blood sample will be taken. Because your child is having this extra visit and providing samples at that time, your child will not be required to have an onsite visit after 3 months or provide samples. Instead, this visit can be done by phone call or telemedicine.

You can also choose for your child to take part in a smaller study called a substudy within this research study. If you decide for your child to participate in this substudy, then your child will receive a BPZE1 nasal vaccination 3 months after their first vaccination. A separate informed consent document will explain the substudy to help you decide if you would like your child to participate in that substudy. This is considered "open label" as every child participating in the substudy will know they have received BPZE1 (unlike the beginning of the study when you/your child and the study doctor do not know what study vaccine was received). There will be 3 extra visits over the course of 1 month after your child receives the BPZE1 vaccination if they are in this sub-study.

The table shows what happens at each visit. All of the tests and visits will be explained by your child's study doctor or study staff trained in this study and able to answer your questions.

VISITS AND PROCEDURES FOR STUDY

Visit	Vaccination	Blood sample	Nasal swab sample	Home eDiary	Second type of nasal sample to test for BPZE1	SARS-CoV-2 test
Day 1	X	X	X	sent	---	X
1 week later (first 45 participants only)	---	X	---	eDiary reviewed	X	
1 month later	---	X	X	eDiary reviewed	½ of remainder of participants	
3 months later	---	X	X	---	½ of remainder of participants	
6 months later	---	X	X	---	----	
SUBSTUDY ONLY						
3 months later	X	X	X	sent	---	X
1 week after	---	---	---	eDiary reviewed	X	
2 weeks after	---	---	---	---	X	
4 weeks after	---	X	X	---		



- **Medical History:** Review of your child's health history, medical conditions in the past or that your child is currently having, and surgeries/important procedures for medical conditions (like endoscopy or removal of tonsils), to make sure your child can join the study.
- **Medications and Vaccinations Review:** Review of medicines and vaccines that your child is receiving or have received just before joining the study. Current medicines will include non-prescription medicines, herbal products, vitamins, and other medications.
- **Personal Health Information (Demographics):** You will be asked for your child's birth date, sex, and race or ethnicity. These data are collected only for clinical research purposes.
- **Limited Physical Examination:** Your child's height and weight will be measured at the first visit. A physical examination, similar to a well child visit, will occur at each visit to ensure your child is healthy and able to participate in the study and receive a vaccination.
- Your child's **heart rate** and **body temperature** will be measured on vaccination days and anytime the clinical staff deems this to be important for your child's health exam.
- **Pregnancy Test:** If your child is female of childbearing potential who has become sexually active, your child's urine will be tested to check that they are not pregnant before joining the study and before any study vaccination. An accepted method of birth control (to reduce the chance of becoming pregnant) needs to be in place if your child is sexually active. The study doctors recognise this can be a sensitive topic and will safeguard these discussions and maintain confidentiality at all times.
- **SARS-CoV-2 (COVID-19)**: Before joining and carrying out any procedures required for the study, your child's study doctor and/or study staff will carry out a test to determine if your child is currently infected with COVID-19. The study doctor and/or study staff will explain to you and your child the details about the procedure, reason for doing it, and what the results may mean. If you are not familiar with any of these procedures, then please ask your child's study doctor to explain how they are done.

- **Subject Diary:** You (or your child if appropriate age to do so) will be required to complete an electronic study diary (eDiary) that collects responses about all reactions that may occur following the vaccination. Your (or your child's) responses will be collected and shared with the researchers of the study. Also, the eDiary is managed via an Oxus Technologies Limited online Web Portal. Further information about how Oxus Technologies Limited manages your data is available here: https://oxustech.com/st-data-privacy-notice/. In order to monitor the reactions following the vaccination, a measurement tool, and a thermometer will be provided at the end of the study vaccination visit with instructions for how to complete the eDiary. For the first 1 week following the first study vaccination, you (or your child if appropriate age to do so) will be asked to record the following:
    - Your child's oral temperature
    - Redness or swelling and pain/tenderness where your child received the vaccination in their arm
    - General symptoms of feeling fatigued, or having muscle aches, headache, nausea or vomiting, diarrhoea, appetite, or a rash develop
    - Nasal/throat symptoms- runny nose or congestion, sore throat, cough, sneezing, nasal or sinus irritation or difficulty breathing.
    - Any medication that contained paracetamol – which may be used to treat or avoid symptoms following vaccination

  If your child is participating in the substudy, then you (or your child if appropriate age to do so) will collect a similar daily record after receiving BPZE1 at 3 months. It is important to complete the entire eDiary every day (documenting even when your child does not have any symptoms).
- These symptoms will also be recorded by the study staff on the day your child receives a vaccination before your child is discharged from study site.
- **Nasal Samples for nasal immunity using a swab/wick:** Your child will be asked to give nasal samples on 4 occasions. A nasal swab/wick inserted into the front of the nose and remaining in place for 2 minutes (see Visits and Procedures for Study Table above). This sample will collect secretions from the nose to see if your child has developed immunity in the upper airway. The swab/wick being used, and the collection methods will be explained and shown to you and your child by the study staff. If your child is participating in the substudy, then 1 more sample will be taken after they receive BPZE1 at 3 months.
- **Nasal Samples taken for BPZE1 testing**: A different type of swab will also be used to collect a nasal sample to test for BPZE1 in your child's nose one time. This swab will also be shown and explained to you and your child by the study staff. If your child is participating in the substudy, then 2 more of these samples will be taken after your child receives BPZE1 at 3 months.

- **Blood Samples:** Your child will be asked to give blood samples on 4 occasions. A local anaesthetic cream (or cold spray) will be offered to reduce any discomfort. Distraction techniques can also be helpful for small children. The table below gives details of the amount of blood that will be taken during each visit and for the entire study. If your child is participating in the substudy, then an additional blood sample will be taken after your child receives BPZE1 at 3 months. The total amount of blood taken over the entire study will be approximately 60 ml (4 tablespoons) for the first 45 participants, approximately 40 ml (3 tablespoons) for standard enrolment, approximately 50 ml (3 tablespoons) for the substudy and an extra 20 ml (4 teaspoons) for the substudy's optional blood donation.
- The exact amount of blood taken at each visit will depend on which type of tube the study site uses for tests, your child's age and body weight. Guidelines are in place to ensure that we do not take too much blood.

STANDARD STUDY VISITS AND MAIN PROCEDURES

Group enrolled	Visit 1 (Day 1)	Visit 2 (1 week later)	Visit 3 (1 month later)	Visit 4 (3 months later)	Visit 7 (4 months later)	Visit 8 (6 months later)	Total
First 45 participants	30 ml (6 tsp)	20 ml (4 tsp)	10 ml (2 tsp)	---	No visit	10 ml (2 tsp)	70 ml (5 Tbs)
Standard enrolment	10 ml (2 tsp)	No visit	10 ml (2 tsp)	10 ml (2 tsp)	No visit	10 ml (2 tsp)	40 ml (3Tbs)
Substudy	10 ml (2 tsp)	No visit	10 ml (2 tsp)	10 ml (2 tsp)	10 ml (2 tsp)	10 ml (2 tsp)	50 ml (3 Tbs)
Substudy Optional blood donation				20 ml (4 tsp)	20 ml (4 tsp)		Extra 40 ml (8 tsp) =3 Tbs in total for sub-study

What is expected from you and your child?

While your child is in the study, we will ask you and your child to do these things:

- Come to all study visits.
- Do not let your child take routine nasal sprays (including steroid sprays) or washes for at least 7 days following any study vaccination.
- Do not let your child use smoking products, vape or use e-cigarettes from enrolment through the first month following any study vaccination.
- Tell the study doctor about any new treatment or medicine your child receives during the study.
- Give correct information about your child's health history and current health.
- Tell the study doctor about any health problems your child has during the study.
- Ensure your child's subject eDiary is complete every day for 7 days after they receive a vaccination.

- If your child is female and becomes pregnant, tell your child's study doctor as soon as you know (for additional information, please see section on "Are there any reproductive risks?" below).
- Be aware that some people on social media have been aggressive to people who have taken part in studies of vaccines in the past so we recommend not posting or discussing about the study on social media.
- Remain in touch with your child's study doctor or study site staff and tell them if you and your child have a change in contact information or if you no longer wish for your child to be in the study. Provide a second contact source to ensure we can always contact you during the study period. The site staff will make numerous attempts to contact you, if you and your child fail to return for a visit (including phone, internet and certified letter by mail).
- Agree to not let your child take part in any other study until at least 85 days following the final study vaccination.
- Avoid your child from routine/repeated contact with, or living in a household with, individual(s) who have an impaired immune system that may not function well. Your child's study doctor will review any concerns in this regard.
- During the vaccination period (at least 85 days following the final vaccination), avoid your child from residing where an infant less than 6 months of age also resides.

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

During the last visit (6 months after your child enrols) you can indicate to your child's study doctor if you wish for your child to receive Boostrix (a licensed vaccine) if your child did not receive it in the trial. This would be at no cost to you or your child. Both you and your child, and the study doctor will determine if your child will benefit from the vaccination and updated contact information will be collected to allow you and your child to get notified once the data are analysed and it is understood what vaccines your child received.

Your child's study doctor and/or ILiAD Biotechnologies may also learn new facts during the study that affect your child's health and you will be told about the new facts. You can then decide if you want your child to still be in the study. If you decide for your child to leave the study, there will be no penalty and you will not lose any benefits your child is entitled to. Leaving the study will not affect the quality of the health care your child is given. The samples collected up to that point will be utilised for the study as outlined unless you indicate otherwise to your child's study doctor.

The study doctor may end your child's participation in this study early for any of the following reasons:

- Staying in the study would be harmful or cause undue burden for your child.
- New treatments or diagnoses make staying in the study difficult or impractical to continue.
- Instructions about what to do in the study are not being followed.
- The study is cancelled.

The study doctor will tell you the reason(s) why your child's participation would be discontinued.

If at a point in the study, your child cannot attend any further visits, but you are willing to be contacted by phone/internet for safety follow-up that is preferred over stopping your child's participation. This is to allow for complete data about your child's health and safety till the end of the study to be collected. If you decide for your child to leave the study early, the study doctor will ask you for your child to attend a final visit to have a health assessment and be able to collect a final set of samples.

What are the potential risks and discomforts?

To date, no serious side effects considered related to the study treatment have been reported. Of research participants in a prior BPZE1 study, the most common reported symptoms following vaccination were:

- Sneezing
- Tiredness
- Headache
- Runny or stuffy nose
- Cough

Most of these symptoms were mild or moderate and lasted only a few days. The atomizer is used to deliver the vaccine. It is not placed into the nose, but only against the surface. There are no risks associated with its use, but assessment will be performed after vaccination to ensure no injury was noted.

The side effects of Boostrix are well studied and the most common side effects include the following:

- Pain, redness, and swelling at the injection site
- Headache
- Feeling tired or sleepy
- Loss of appetite

- Fever

Fainting can occur in association with administration of injectable vaccines.

You will be given a patient information leaflet about Boostrix and its side effects as this is a licensed vaccine.

Your child can also experience side effects of the tests they receive during the study such as the following:

- Nasal samples: Nasal samples can be uncomfortable, but this should clear up in a short period of time. Call your child's study doctor right away if they have any side effects that you think are serious.
- Blood sample collection: Pain, redness, soreness, bruising, or infection may occur at the needle stick site. The study doctor may put some cream or cold spray on your child's skin to numb the area so they will not feel the needle as much. The numbing cream may make your child's skin have a change in colour, but this is rare. Bruising can be prevented or reduced by putting pressure on the blood collection site for a few minutes after the blood is collected. It is possible to get an infection from having blood collected. This is not very likely. To reduce the risk of infection, the area where the blood will be collected will be cleaned using aseptic technique. Sterile equipment will be used. Rarely, some individuals experience fainting, dizziness and nausea during blood collection due to a vasovagal reaction. If this has happened to your child in the past, please inform the phlebotomist so appropriate precautions (for example, lying flat, avoid watching) can be taken. If your child does not feel well while the blood is being taken from them or after it has been taken, please tell the study doctor or a member of the study team.

Risks that are not known:

The vaccine used in this study (BPZE1) is experimental. There may be risks that are unknown. Study staff will update you in a timely way on any new information that may affect your child's health, welfare, or decision to stay in the study.

Allergic Reaction

Sometimes, people have serious allergic reactions to vaccines. A severe allergic reaction could be life-threatening and may result in death. Symptoms of allergic reactions include the following:

- Rash, hives or general itching
- Shortness of breath or wheezing or chest tightness
- Extreme swelling (at an injection site or generalised)

Most severe allergic reactions to vaccines happen fairly quickly. These reactions can be treated effectively if the appropriate medicines and equipment are close at hand. As a

precaution, your child will stay at the study site for 30 minutes following vaccination. So far, no severe allergic reactions have happened in people who received BPZE1, but since such reactions to vaccines are rare, it remains possible that this could happen in the future. Severe reactions to Boostrix are very rare.

Are there any reproductive risks?

If your child is pregnant, planning to become pregnant, or are currently breastfeeding, they cannot take part in this study. Females who are sexually active and therefore could become pregnant must have a pregnancy test to rule out pregnancy before they are vaccinated. After joining the study, female participants must report immediately to the study site if they suspect or know they are pregnant during the study. The study doctor will advise you and your child about your child's health care and will ask about your child's pregnancy and its outcome, including the health of your child's baby for safety reasons. The study doctor will arrange for your child to be counselled by a specialist, in order to discuss the risks of continuing with the pregnancy and the possible effects on the foetus. You (and your child) will be asked to sign (either in wet ink or electronically) a new consent form to allow collection of data about the health of your child's baby. Your child's personal information will be collected, but their privacy and that of their newborn child will be protected by limiting access to personal information that may identify individuals, such as names, contact details, and any government-issued identification numbers.

If your child is female and able to have children and is having sex with any male, your child must agree to be heterosexually inactive from at least 21 days prior to enrolment and through 90 days following any study vaccination, or agree to consistently use any of the following methods of birth control from at least 21 days prior to enrolment and through 90 days following any study vaccination:

- Condoms (male or female) with or without spermicide*
- Diaphragm with or without spermicide*
- Cervical cap with or without spermicide*

* The highest level of protection is required, in accordance with local regulations.

- Intrauterine device
- Oral or patch contraceptives
- Norplant®, Depo-Provera®, or other acceptable method of birth control that is designed to protect against pregnancy.

NOTE: Periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods) and withdrawal are not acceptable methods of birth control.

You must discuss with your child's study doctor the type of birth control method that your child uses before they begin the study. The study doctor must approve the method your child uses before they can enter the study.

Are there any possible benefits of being in the study?

Taking part in this study may or may not help to protect your child against whooping cough (pertussis). Your child's health could improve, stay the same, or get worse regardless of participation. However, the data we get from your child during this study may help doctors learn more about the study vaccine and the disease, and this may help people who may receive such vaccines in the future. If your child receives Boostrix in this study, it has a known benefit to stop severe pertussis infections. Your child has a 66% chance of receiving Boostrix.

Are there any other choices?

Instead of participating in this study, you may choose for your child to:

- Get treatment without being in this study
- Join a different study
- Get no treatment

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

If new information such as any safety findings potentially associated with BPZE1 emerge during the study you will be informed and an update to the informed consent would occur. If you decide for your child to not to carry on in the study, your child's study doctor will make arrangements for their care to continue. The overall immunity induced by BPZE1 will be shared with you when the results are published, and the vaccines your child received. However, individual immunity results to pertussis will not be available.

Who is carrying out the study?

The study is being carried out in the NHS and Universities by researchers including those at Bristol Vaccine Centre. Study doctors and nurses at the NHS or University sites do not receive payment for running studies in the NHS, although the NHS is fully funded by the study Sponsor (pharmaceutical company) for the study to take place. The sponsor of this study is a company named ILiAD Biotechnologies. The study will be supervised by the study doctor, who is named on the first page of this consent.

Expenses and payments

You and your child will not receive payment for taking part in this study, but you will receive a £10 Amazon voucher for each visit as a thank you for your and your child's time. You may be given money back for travel (bus/train/taxi fares), you have as a result of your child taking part in this study if you provide a receipt.

Who is funding this research?

ILiAD Biotechnologies is organising and funding the study. ILiAD Biotechnologies or a designee will reimburse the hospital or study site (NHS or University site) to cover its costs to conduct the study.

What if there is a problem?

Complaints
If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions **0117 342 0174 / 0117 342 0160.** If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. We recommend that you obtain a copy of your child's hospitals complaints procedure or policy if you intend to make a complaint.

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

ILiAD Biotechnologies will pay compensation where the injury probably resulted from:

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

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

ILiAD Biotechnologies would not be bound by these guidelines to pay compensation where:

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

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

If you think your child has an injury/illness that is related to the study, you should immediately tell **Dr Jolanta Bernatoniene,** the study doctor, or one of the staff members working on the study. The study doctor and the study staff may be reached at 0117 342 0174 / 0117 342 0160.

How will your child's confidentiality be respected, and the privacy of your child's personal information maintained?

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

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

To ensure privacy, your child's name and other directly identifying information will not be attached to records or samples released to ILiAD Biotechnologies and its service providers for research purposes. Instead, your child will only be identified by a code. Only the study doctor and authorised personnel will be able to connect this code to your child's name, by a list that will be kept securely by the study site for 15 years. Your child's date of birth may also be recorded to help identify your child's study record. Your child's coded data will be forwarded to ILiAD Biotechnologies and its service providers for activities related to the study e.g. laboratory analysis. A list of companies to whom your child's coded information is transferred is available from the ILiAD Biotechnologies via your child's study doctor.

Under the Data Protection Act 2018 ILiAD Biotechnologies makes important decisions on how your child's information collected for the research project are used and disclosed and is responsible as 'controller' for ensuring that the rules of this law are followed. ILiAD Biotechnologies has appointed Synexus Clinical Research Limited as its 'representative' to fulfil its obligations under this law. The study site will have similar responsibility in respect to the handling of data in your child's medical files at site.

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

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

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

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

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

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

If you have any questions, comments or complaints about how your child's information is handled in this study, or wish to obtain a copy of the Standard Data Protection Clauses, you should firstly contact your child's study doctor who will be able to direct your query where appropriate to staff responsible for data protection at the ILiAD Biotechnologies or site, including the site Data Protection Officer.

What happens to the samples collected from your child?

Nasal, blood, and urine (for pregnancy test) samples will be taken from your child in this study. Your child's samples will be tested on site or sent to laboratories identified to conduct research on BPZE1 (these laboratories are worldwide, including Australia, North America, the European Union or the UK) for ILiAD Biotechnologies who will test your child's immunity and the presence of BPZE1 in your child's nose. Samples will be identified by a code and your child's date of birth. Your child's date of birth will be entered on study's data form. Some of your child's samples may be retained for additional testing of biological responses for future research and will be securely stored for up to 15 years (starting from the date at which the last participant had the last study visit), unless local rules, regulations, or guidelines require different time frames or different procedures, and

per your consent. After this time, your child's samples will be destroyed. Anyone who works with your child's samples will keep the coded samples and the results private.

During and after the study, you will keep the right to have the samples destroyed if you contact your child's study doctor, as long as your child's samples are still coded and can be found. If you wish for your child to leave the study, your child's samples may not be destroyed unless you specifically request this to your child's study doctor or team. All the samples and test data collected before your child left the study will still be used for study purposes. After your child leaves this study, no new samples or new information will be collected from your child for the study.

Any samples collected from your child that are remaining after all tests have been completed will be used for future research. This means that the samples may be tested for the following purposes:

- To learn more about the effects of BPZE1 on the body's immune system,
- To develop new drugs or devices, tests, or processes, including commercial products, for which BPZE1 may be effective,
- To understand the pertussis infection and how the body responds to pertussis, tetanus, or diphtheria.

Has the study received medical or ethical approval?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your child's interests. This study has been reviewed and given favourable opinion by the Fast Track Research Ethics Committee.

Involvement of the General Practitioner/Family doctor (GP)

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

Who can you contact with further questions?

You may ask questions about this information sheet and consent form or the study at any time (before or during the course of the study). If you have additional questions, or experience a research-related injury, contact the study doctor **Dr Jolanta Bernatoniene** or the study support staff on **0117 342 0174 / 0117 342 0160**

For any questions about your child's rights as a research participant, please direct enquiries to:
Patient Support and Complaints:
Address: The Welcome Centre, Level 2, Bristol Royal Hospital for Children, Bristol, BS2 8AE

Tel: 0117 342 1050
Email: psct@uhbristol.nhs.uk

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

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

INFORMED CONSENT FORM

Principal Investigator: **Dr Jolanta Bernatoniene**

Participant Number: _____

Participant Initials: _____

Short Title: Phase 2b Study of BPZE1 Vaccine in Healthy School-Age Children

Statement of Consent	*Please Initial Box:*
What will happen to your data? By signing this form, you provide consent for your child's information to be collected, used and shared as described: – The authorised representatives of Sponsor, and regulatory authorities' inspectors may have direct access to your child's medical records. – Study data, including your child's coded medical information, may be retained and later used for further research into your child's medical indication, unless you object. – Study data may be transferred to other countries for study purposes, including countries that do not provide the same standard of legal protection for your child's personal information as in the United Kingdom.	
I have read and understand the statements in this informed consent form.	
I have had the chance to ask questions, and I am satisfied with the answers given to me.	
I am giving my consent as parent/guardian and voluntarily agree for my child to take part in this study.	
I understand that I will receive a copy of this signed and dated written informed consent form.	
I understand that ILiAD Biotechnologies will use the nasal and blood samples for future research with BPZE1, understanding pertussis associated disease(s) and immunity and developing new therapies using BPZE1.	
I agree to my child's GP being informed of their participation in the study as described in this information sheet	

INFORMED CONSENT FORM

Principal Investigator:	**Dr Jolanta Bernatoniene**
Participant Number:	_____
Participant Initials:	_____
Short Title:	Phase 2b Study of BPZE1 Vaccine in Healthy School-Age Children

_____

Printed Name of Participant, in full

_____

Printed Name of Parent/Legal Guardian, in full

_____

Signature of Parent/Legal guardian **Date (dd-Mmm-yyyy)**

INFORMED CONSENT FORM

Principal Investigator:	**Dr Jolanta Bernatoniene**
Participant Number:	_____
Participant Initials:	_____
Short Title:	Phase 2b Study of BPZE1 Vaccine in Healthy School-Age Children

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

_____

Printed Name of Person Obtaining Consent (Investigator/Delegate), in full

_____

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

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