INFORMATION SHEET FOR PARENTS/GUARDIANS

STUDY TITLE	Prospective, randomised, double-blind, placebo-controlled multicenter clinical trial of efficacy and safety with *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae* mannan-conjugated allergoids in patients with rhinitis/rhinoconjunctivitis,allergic to *Dermatophagoides pteronyssinus* and/or *Dermatophagoides farinae*
STUDY CODE	MM09-SIT-069
SPONSOR	INMUNOTEK S.L.
STUDY DOCTOR	
CENTRE	
CONTACT Email/telephone	
24-HOUR CONTACT Telephone	

INTRODUCTION

We are writing to inform you about a research study in which your child is invited to take part, also known as a clinical trial. The study has been approved by the Portuguese Ethics Committee for Clinical Research (CEIC) and by the National Authority for Medicines and Health Products I.P. (INFARMED) in accordance with current legislation: European Regulation 536/2014 of 16 April, which regulates clinical trials involving medicinal products; Decree-Law No. 102/2007 (Good Clinical Practice); EU Regulation 2016/679 of 27 April 2016 (General Data Protection Regulation – GDPR); Law No. 58/2019 of 8 August, which ensures the implementation of the GDPR within the national legal framework; and Decree-Law No. 176/2006 of 30 August (Medicines Act), as currently in force.

Our aim is to provide you with accurate and sufficient information so that you can decide whether or not you wish your child to take part in this study. Please read this information sheet carefully. We will answer any questions you may have.

In addition, you may seek the opinion of anyone you consider appropriate.

VOLUNTARY PARTICIPATION

Your child has been invited to take part in the study because they have been diagnosed with allergic rhinitis/rhinoconjunctivitis, with or without mild to moderate asthma.

Please be aware that your child's participation in this study is voluntary and that you may decide that your child will NOT take part. If you decide that your child will take part, you may change your mind and withdraw your consent at any time, without this affecting your child's relationship with the study doctor or resulting in any detriment to your child's healthcare.

The sponsor will not follow up with participants once they have completed the study.

AIM OF THE STUDY

Immunotherapy (allergy vaccines) is currently the only available treatment that addresses the root cause of the condition and involves the administration of vaccines over a specific period of time.

The other medicines your child has probably already taken are symptomatic treatments for the condition, which means they do not treat the cause of the allergy, but only the troublesome symptoms when they occur. This is precisely why this study will be conducted using a vaccine designed to treat house dust mite allergy.

The safety and clinical efficacy of a vaccine will be tested by comparing it with a placebo treatment. The ultimate aim is to determine whether the vaccine is safe and effective for treating your child's allergy.

STUDY DESCRIPTION

[redacted]

[redacted]

RISKS AND DISCOMFORT RESULTING FROM PARTICIPATION IN THE STUDY

Please note that the vaccine under investigation is not commercially available. However, there is a great deal of information available to the public regarding the side effects of immunotherapy (allergy vaccines).

The disadvantages of your child's participation in the study include possible adverse reactions to the treatment and to the diagnostic skin test, the need to attend appointments, as well as the risks associated with any blood sampling, such as pain, bleeding, bruising and, in very rare cases, infection at the injection site.

Adverse reactions that may occur during allergy treatment can be classified into two groups:

- Local reactions:

  Redness, swelling, itching or hardening at the injection site are common.

- General/systemic reactions:

  These include feeling unwell, dizziness, gastrointestinal discomfort, nasal symptoms (itching, runny nose, congestion or itching), eye symptoms (itching, redness), difficulty breathing, coughing, wheezing, as well as rarer symptoms such as vaginal bleeding and even more serious reactions such as a generalised allergic reaction, known as anaphylaxis, although this is very rare.

Anaphylaxis can include symptoms such as itching and redness on the palms of the hands and soles of the feet, a feeling of warmth, a rapid heart rate, difficulty breathing and low blood pressure, amongst others. In between these extremes, symptoms such as sneezing, hives, and irritation of the eyes and nose may occur.

These reactions occur relatively infrequently, and their likelihood depends mainly on the symptoms your child usually experiences before vaccination. If these symptoms occur, contact your doctor immediately.

Due to these possible adverse reactions, your child will need to remain in the Allergy Department for at least 30 minutes after the first subcutaneous administration of the vaccine. This is standard practice both for participation in the study and for routine treatment, and the study doctor is on hand to intervene if necessary. For the following three hours, your child must not engage in strenuous physical exercise or have a bath in hot water, although they may have a shower.

POSSIBLE BENEFITS

[redacted]

NOTICE REGARDING PREGNANCY

[redacted]

[redacted]

PARTICIPANTS' OBLIGATIONS

If you agree to your child taking part in this study, they must:

- Attend the study visits and carry out the study activities scheduled by the research team.
- Inform the research team of any adverse events that occur during the study.
- Inform the research team of any changes to their child's medication. Except in an emergency, you must not change the medication your child is taking or give them any other medicines or 'herbal remedies' without first consulting the study doctor.
- Please inform the research team if your daughter becomes pregnant or if your son's partner becomes pregnant at any time from the start of the study until its completion.
- Follow all instructions given by the research team.
- Answer all questions from the research team truthfully.

ALTERNATIVE TREATMENTS

[redacted]

EXPENSES AND FINANCIAL COMPENSATION

The study involves specific research work, so both the hospital and the professionals taking part in the study, including the research team, will receive financial compensation. The study sponsor is responsible for managing the study's funding. To carry out the study, the sponsor has signed a contract with the study doctor and the centre where the study will take place.

You will not have to pay for the study medicines or the specific tests carried out as part of the study. Your child's participation in the study will not incur any additional costs beyond those associated with their usual clinical care.

Your child's participation in the study does not entitle them to any salary or remuneration; this is not permitted by law. However, your child will be reimbursed for expenses incurred as a result of their participation in the study (for example, meals, parking and travel costs) up to a maximum of €40 (forty euros) per visit. Please keep all receipts relating to these expenses.

In the event of loss of earnings during the study due to your child's participation in it, you will be entitled to compensation for lost earnings upon provision of supporting evidence. To be considered eligible for reimbursement, your child must submit the necessary documents, including a statement from their employer or proof from Social Security indicating that they are not receiving sickness or unemployment benefit. Reimbursement of expenses and lost wages also applies to accompanying persons in the case of underage participants.

The study centre's finance department will need access to the necessary details to process the financial compensation. A receipt must be issued for each amount received that may be subject to tax.

WHAT TREATMENT WILL I RECEIVE AT THE END OF THE CLINICAL TRIAL?

[redacted]

[redacted]

INSURANCE

The study sponsor holds an insurance policy that complies with current legislation (European Regulation 536/2014 and Article 15 of Law 21/2014), and will provide compensation and indemnity in the event of harm to your child's health or injuries that may occur in connection with their participation in the study, provided that these are not a consequence of the disease under investigation or the progression of their disease as a result of the treatment's ineffectiveness. The insurance covers pecuniary and non-pecuniary damages caused to participants by the trial whilst the clinical trial is ongoing and for one year following its completion. If you would like further information on this section, please speak to the trial doctor at your centre.

Please be aware that your child's participation in this clinical trial may affect the general and specific terms (coverage) of your insurance policies (life, health, accident, etc.). We therefore recommend that you contact your insurer to determine whether your child's participation in this study will affect your existing insurance policy.

The insurance policy will only cover those taking part in the study. If the partner of a male participant in the clinical trial becomes pregnant, neither the woman nor the baby will be covered by the insurance.

In the event of pregnancy, neither the participant nor the baby will be covered by the insurance policy taken out by the sponsor, as, as indicated in the 'Pregnancy Notice' section, the participant will be withdrawn from the study.

PROTECTION OF PERSONAL DATA

The processing, disclosure and transfer of the personal data of all participants will comply with the legislation in force (Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, on the protection of personal data and Law No. 58/2019 of 8 August) and may exercise their rights of access, rectification, objection and erasure of data, as well as the right to restrict the processing of incorrect data, request a copy or request the transfer of data to third parties; to do so, they should contact the study doctor.

Please note that the data cannot be deleted, even if your child ceases to participate in the study, in order to ensure the validity of the study and to comply with legal obligations and the authorisation requirements for medicinal products.

Your child also has the right to lodge a complaint with the "CNPD – National Data Protection Commission" (Av. D. Carlos I, 134 - 1º, 1200-651 Lisbon). For further information about the CNPD,

please visit the website www.cnpd.pt.

The data collected for the study will be identified by a code, in such a way that it will not include any information that could lead to the identification of your child, and only your child's study doctor and/or staff members will be able to link this data to your child and their medical history. Appropriate safeguards will be put in place to protect your child's coded data during and after the clinical trial. Consequently, your child's identity will not be disclosed to anyone, except in the event of a medical emergency or where required by law. Only representatives of the health authorities, members of the Ethics Committees and authorised staff of the sponsor (monitors and auditors, via your study doctor) will have access to verify personal data, study procedures and compliance with good clinical practice. Should the study monitors and/or auditors require remote access to your child's de-identified data, this will be shared securely. All persons and organisations with access to your child's personal data are bound by professional confidentiality.

If your child suffers harm whilst participating in the study, the study doctor's team may need to share your child's unencoded personal and health data with the insurance company responsible for the study's insurance policy, in order to settle your child's claim for compensation.

The study doctor and the sponsor are required to retain the data collected for the study for at least 25 years after its completion. Thereafter, your child's personal information will be retained by the centre for the purposes of their healthcare.

If we transfer your child's encrypted data outside the EU, participants' data will be protected by safeguards, such as contracts or other mechanisms, put in place by the data protection authorities. If you would like further information on this matter, you may contact the **sponsor's Data Protection Officer** [redacted]

WHAT WILL HAPPEN TO THE STUDY RESULTS?

[redacted]

OTHER RELEVANT INFORMATION

Any new information regarding the medicines used in the study that may affect your child's [redacted]

CLINICAL TRIALS INVOLVING MINORS

Please note that, regarding your child's participation – who must be at least 12 years old – they will be given an information sheet and an informed consent form adapted to their level of understanding, which they must sign if they wish to take part in the study.

COLLECTION AND USE OF BIOLOGICAL SAMPLES

[redacted]

[redacted]

INCIDENTAL FINDINGS

[redacted]

[redacted]

CONTACT IN CASE OF QUESTIONS

If, whilst your child is taking part in the study, you have any questions or require further information, please contact the study doctor at your centre, whose contact details are provided on the first page of this document.

For matters relating to data protection, please contact the centre's data protection officer via email <add email>:_____.

Any questions regarding your child's rights and responsibilities as a participant in this clinical trial may be addressed to the following independent body, which has reviewed and approved this trial:

[redacted]

ACKNOWLEDGEMENTS

Whatever your decision, the sponsor and the research team thank you for your time and attention.

parents/guardians INFORMED CONSENT

STUDY TITLE: Prospective, randomised, double-blind, placebo-controlled multicenter clinical trial of efficacy and safety with *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae* mannan-conjugated allergoids in patients with rhinitis/rhinoconjunctivitis,allergic to *Dermatophagoides pteronyssinus* and/or *Dermatophagoides farinae*

I, ...(mother's/guardian's first name and surname)

as the mother/guardian of ……..……...

(participant's first name and surname)

- I have read the information sheet provided to me.
- I had the opportunity to ask questions about the study.
- I have received sufficient information about the study.

I spoke to .....(name and surname of the researcher)

I understand that participation is voluntary and that I can withdraw from the study:

1. whenever I wish.
2. Without giving any reason.
3. Without this affecting their medical care.

I give my free and informed consent for him/her to take part in the study and authorise access to and use of the data under the conditions described in the information sheet.

I, ...(father's/guardian's first name and surname)

as the parent/guardian of.……...

(participant's first name and surname)

- I have read the information sheet provided to me.
- I had the opportunity to ask questions about the study.
- I have received sufficient information about the study.

I have discussed with.…… (name and surname of the researcher)

I understand that participation is voluntary and that he or she may withdraw from the study:

1. whenever they wish.
2. Without giving any reason.
3. Without this affecting their medical care.

I give my free and informed consent for their participation in the study and authorise access to and use of the data under the conditions described in the information sheet.

A summary of the clinical trial results and a summary presented in terms understandable to a layperson will be made available in the EU database (https://euclinicaltrials.eu/search-for-clinical-trials/?lang=pt).

We will receive a signed and dated copy of this information sheet and the informed consent form.

Please tick the appropriate box to authorise the child's participation in the study:

☐ The parents (both)

MOTHER'S SIGNATURE Date: ___/___/_____	**FATHER'S** SIGNATURE Date: ___/___/_____
Signature of **the STUDY DOCTOR** Date: ___/___/_____	

(Handwritten signature and date)

☐ The signatory is the sole legal guardian.

Signature of **the LEGAL GUARDIAN** Date: ___/___/_____	Signature of **the STUDY DOCTOR** Date: ___/___/_____

I would like to be informed about incidental findings that have an impact on the child.	Yes ☐	No ☐
I would like to be informed about incidental findings that have an impact on the child's family.	Yes ☐	No ☐
I agree that the child's attending doctor should be informed of any incidental findings.	Yes☐	No ☐

☐ The parents (both)

Mum's signature Date: ___/___/_____	**FATHER'S** SIGNATURE Date: ___/___/_____
Signature of **the STUDY DOCTOR** Date: ___/___/_____	

(Handwritten signature and date)

☐ The signatory is the sole legal guardian.

Signature of **the LEGAL GUARDIAN** Date: ___/___/_____	Signature of **the STUDY DOCTOR** Date: ___/___/_____

INFORMED CONSENT before witnesses

STUDY TITLE: Prospective, randomised, double-blind, placebo-controlled multicenter clinical trial of efficacy and safety with *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae* mannan-conjugated allergoids in patients with rhinitis/rhinoconjunctivitis,allergic to D*ermatophagoides pteronyssinus* and/or *Dermatophagoides farinae*

.....I, (witness's first name and surname)

in my capacity as a witness, hereby state that, in my presence, Mr/Ms .....

(participant's first name and surname)

- read (or had it read to them, in the event that the participant cannot read) and understood the information leaflet provided to them.
- They had the opportunity to ask questions about the study.
- They received sufficient information about the study.

Spoke to .....(name and surname of the researcher)

Understands that their participation is voluntary and that they may withdraw from the study:

1. Whenever you wish.
2. Without giving any reason.
3. Without this affecting your medical care.

Within the limits of the law, you authorise the access, use and sharing of your personal data, as described in the section 'Protection of personal data'.

The participant has received a signed and dated copy of this information leaflet and the informed consent form. Yes ☐ No ☐

The participant wishes to be informed of incidental findings that have an impact on themselves.	Yes ☐ No ☐
The participant wishes to be informed about incidental findings that have an impact on their family.	Yes ☐ No ☐
The participant agrees that their attending doctor should be informed of any incidental findings.	Yes☐ No ☐

The participant freely consents to taking part in the study. Yes ☐ No ☐

WITNESS'S SIGNATURE *(As per ID card)* Date: ___/___/_____	Signature of **the STUDY DOCTOR** Date: ___/___/_____

(Handwritten signature and date)