PARTICIPANT INFORMATION SHEET

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-063
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 you are 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 to take part in this study. Please read this information sheet carefully. We will answer any questions you may have.

Furthermore, you may seek the advice of anyone you consider appropriate.

VOLUNTARY PARTICIPATION

You have been invited to take part in the study because you have been diagnosed with allergic rhinitis/rhinoconjunctivitis, with or without mild to moderate asthma.

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

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

AIM OF THE STUDY

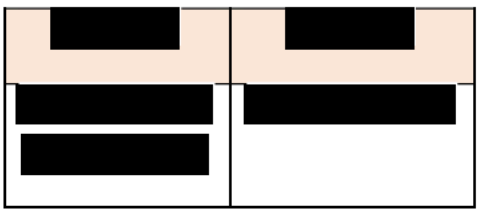
Immunotherapy (allergy vaccines) is currently the only available treatment that addresses the root cause of the condition and involves the administration of vaccines over a specific period of time.

The other medicines you have 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 allergy.

STUDY DESCRIPTION

[redacted]



You [redacted]

[redacted]

[redacted]

RISKS AND DISCOMFORT RESULTING FROM YOUR 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 drawbacks of your participation in the study include possible adverse reactions to the treatment and 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 you usually experience before vaccination. If these symptoms occur, contact your doctor immediately.

Due to these possible adverse reactions, you 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 your study doctor is prepared to intervene if

necessary. For the following three hours, you should not engage in strenuous physical exercise or take a hot bath, although you may take a shower.

POSSIBLE BENEFITS

[redacted]

NOTICE REGARDING PREGNANCY

[redacted]

- [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

PARTICIPANTS' OBLIGATIONS

If you agree to take part in this study, you 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 your medication. Except in an emergency, you must not change the medication you are taking or take any other medicines or 'herbal remedies' without first consulting the study doctor.
- Inform the research team if you become pregnant or if your partner becomes pregnant 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

[redacted]

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

[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 damage to your health or injuries that may occur in connection with your participation in the study, provided that these are not a consequence of the disease under investigation or the progression of your disease as a result of the treatment's ineffectiveness. The insurance covers pecuniary and non-pecuniary damages caused by the study to participants during the clinical trial and in the year following its completion. If you would like further information on this section, please consult the study doctor at your centre.

Please be aware that your 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 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). You may exercise your rights of access, rectification, objection and erasure of data, and may restrict the processing of data that is inaccurate, request a copy or its transfer to third parties; to do so, you should contact your study doctor.

If you decide to withdraw your consent to participate in this study, the data collected up to that point will continue to be used for the purposes described and will be stored in accordance with legal requirements, to ensure the validity of the study and to comply with legal obligations and the authorisation requirements for medicinal products.

You also have 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 your identification, and only your study doctor and/or the research team will be able to link this data to you and your medical history. Appropriate safeguards will be put in place to protect your coded data during and after the clinical trial. Consequently, your 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 de-identified data, this will be shared securely. All individuals and organisations with access to your personal data are bound by professional confidentiality.

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

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 personal information will be retained by the centre for your healthcare.

If we transfer your 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 RESULTS OF THE STUDY?

[redacted]

OTHER RELEVANT INFORMATION

[redacted] case [redacted]

[redacted]

COLLECTION AND USE OF BIOLOGICAL SAMPLES

Your participation in this clinical trial involves the collection and use of biological samples (blood).

[redacted]

[redacted]

INCIDENTAL FINDINGS

[redacted]

CONTACT IN CASE OF QUESTIONS

If, during your participation, you have any queries 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 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.

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, (participant's first name and surname) .....

- I have read and understood the information sheet provided to me about the study.
- I have 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 my participation is voluntary and that I may withdraw from the study:

1. Whenever I wish.
2. Without giving any reason.
3. Without this affecting my medical care.

Within the limits of the law, I authorise the access, use and sharing of my personal data, as described in the section 'Protection of personal data'. Yes ☐ No ☐

I confirm that I have received a signed and dated copy of this information sheet and the informed consent form. Yes ☐ No ☐

I wish to be informed about incidental findings that may affect me.	Yes ☐	No ☐
I wish to be informed about incidental findings that may affect my family.	Yes ☐	No ☐
I agree that my attending doctor should be informed of any incidental findings.	Yes ☐	No ☐

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).

I freely consent to taking part in the study.

Signature of the **PARTICIPANT** *(as per ID card)* Date: ___/___/____	Signature of **the STUDY DOCTOR** Date: ___/___/____

(Handwritten signature and 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 *Dermatophagoides pteronyssinus* and/or *Dermatophagoides farinae*

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

in my capacity as a witness, I 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 sheet 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)

You understand that your participation is voluntary and that you 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 sheet and the informed consent form. Yes ☐ No ☐

The participant wishes to be informed of incidental findings that may affect them. Yes ☐ No ☐
The participant wishes to be informed about incidental findings that have implications for 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)