

Participating Clinician Information Sheet

Study Title	CHOICE: “Criteria Used by Health Professionals on the Selection of Allergen Immunotherapy in Real Clinical Practice: an international e-survey”.
National Study Coordinators	Prof. Constance Katelaris, Head of Immunology, Campbelltown Hospital Dr Narinder Kaur, Clinical Immunologist and Allergist Dr Margaret Li, Allergy and Immunology Fellow, SCHN
Site-Specific Contact Person	Dr Margaret Li, Allergy and Immunology Fellow, SCHN Margaret.li@health.nsw.gov.au

1. Introduction

You are invited to take part in a research study titled **CHOICE**. This study will be conducted at multiple sites in NSW and in other states of Australia in conjunction with the International collaborators across the world including Europe, Latin America, China, Middle East, Japan, Canada, Russia and some Arabic countries

This information sheet tells you about the study. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the study. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about.

Participation in this research is voluntary. If you do not wish to take part, you do not have to.

2. What is the purpose of this study?

The Aim of the project is:

- a. To identify the key factors/criteria that drive the selection of allergen immunotherapy (AIT) in patients with environmental respiratory allergies in real life clinical setting.
- b. To establish the priority of different factors/criteria used by the participants

This is a survey-based research. The purpose of this research does NOT include obtaining a degree or other educational qualification by the researchers.

3. Why have I been invited to this study?

You are invited to take part in this study because you are a clinician who currently prescribe aeroallergen immunotherapy as part of their regular clinical practice to treat adults and children, suffering from IgE-mediated respiratory allergy to environmental allergens (such as pollen, house dust mites, animal dander and moulds) in real life setting.

4. Do I have to take part in this study?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with ASCIA or any professional staff associated with this study.

If you do decide to take part, please contact the study co-ordinators. Completion of the survey / questionnaire will be taken as your consent.

5. What does participation in this study involve?

If you decide to take part in this study, you will be given a unique clinician study code which you will use for the duration of the project. You will be required to fill in a one-off Doctor's Questionnaire (DQ) via online platform "SurveyMonkey©" which will collect de-identified data on your current aeroallergen immunotherapy prescribing practices.

You will be required to identify eligible participants patients in whom you are planning to commence aeroallergen immunotherapy as part of your standard practice, and to provide them with the appropriate invitation letter and information sheet and obtain written consent for their participation in the research.

You will be required to complete a separate Patient's Questionnaire (PQ) via the same online platform "SurveyMonkey©" for each individual eligible patient participants who have consented. The information entered into the PQs must be de-identified and will include demographics, relevant past medical history, and any relevant diagnostics tests which have already been completed as part of the patient's standard care.

Both the DQs and PGs are short and not expected to take longer than 5-10 minutes to complete. We estimate each clinician participant should recruit around 10 patients during our intended study period of 12 months.

6. What are the possible risks and disadvantages of taking part?

There is minimal risk involved in taking part in this study as it is a non-interventional, observational study and does not require you to alter any clinical decisions or standard care provided to your patients. You are not required to perform any additional investigations or treatments for your patients, other than what would already be your standard of care. The online questionnaire will take around 5-10 minutes will only need to be completed once for each participating patient.

There may be a potential theoretical risk of privacy, however, the data collected is de-identified and anonymous. You will be assigned a unique study code number. Only the data managers of the CHOICE project will have the ability to link this code number with your personal information.

None of your participating patients' identifiable data will be collected or stored. The data managers will not have access to identifiable data of patients. Therefore risk of privacy of your participating patients will be non-existent.

7. What are the possible benefits of taking part?

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There will be no benefit to you from your participation in this study. However, we hope that by conducting this study, more information and knowledge can be gained about current clinical practices in prescribing aeroallergen immunotherapy which will lead to better evidence-based practice in the future and improved patient outcomes.

8. What will happen to my information?

Your privacy and confidentiality will be protected at all times. Your information will only be used for the purpose of this research study and it will only be disclosed with your permission, except as required by law. For example, researchers are required to report if a participant is believed to be at risk of harm.

In order to protect your privacy, the study team will remove any information that may be used to identify you from any study documents, and instead of your name appearing on the documents, you will be identified by a specific study code number that applies only to you. Only this code number will be used on any research-related information collected about you for this study, so that your identity as part of the study will be kept completely private. Only the data managers of the CHOICE project will have the ability to link this code number with your personal information, and the linking information will be kept in University Hospital of Montpellier (France) following the current European legislation on data protection. This data will be stored for 1 year after the study finishes.

The de-identified anonymous database will be stored for 7 years after the study finishes on secured servers at the Sydney Children's Hospital Network, NSW, Australia.

If you withdraw from the study, we will not collect any more information about you or any patients you have consented to participate in the study. We would like to keep the information we have already collected about you and your patient participants to help us ensure that the results of the research project can be measured properly. Please let us know if you do not want us to do this.

9. How will the results of the study be distributed?

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your expressed permission.

You can indicate on the consent form if you wish to receive a lay summary of the study findings.

10. Who should I contact if I have any questions?

If you have any questions or want more information about this study before or during participation, you can contact **Dr Margaret Li on Margaret.li@health.nsw.gov.au**

11. Who do I contact if I have concerns about the study?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This study has been approved by the Sydney Children's Hospitals Network (SCHN) HREC (2022/ETH00416).

If you have any concerns or complaints about any aspect of the project or the way it is being conducted, you may contact the Executive Officer of the SCHN HREC on (02) 9845 1253 or SCHN-Ethics@health.nsw.gov.au.

This Information Sheet is for you to keep. We will also give you a copy of the signed consent form.