PARTICIPANT INFORMATION SHEET

Non-Interventional Study: Adult providing own consent

Study Title:	Assessment of the hereditary angioedema (HAE) IMPACT PRO Tool and validation of the HAE IMPACT Score in Australian patients with HAE C1-INH deficiency types 1 and 2
Short title	HAE IMPACT PRO Tool: Assessment and validation
Study Number:	HAE-AUS-001-2023
Study Sponsor:	HAE Australasia Limited
Principal investigator	Professor Connie Katelaris, Allergy and Immunology Services, Suite 308, 151 Hawkesbury Road, Westmead, NSW
Associate Investigator	Dr Raymond Mullins, Consultant Allergy and Immunology Specialist, Allergy Capital, Deakin ACT
Study location(s):	One time online data capture

Introduction

You are invited to take part in this research project. This is because you have previously been diagnosed with hereditary angioedema (HAE) and are currently receiving management for this condition. This research project aims to assess a newly developed patient questionnaire – the HAE IMPACT PRO Tool.

This Participant Information Sheet and Consent Form tells you about the research project. It explains the research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to the research that is described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

What is the purpose of this research?

The symptoms of HAE include episodes of oedema (swelling) in various body parts including the hands, feet, face and airway. The unpredictable, potentially life-threatening, nature of these episodes places a considerable burden on patients. There is no cure for HAE.

Current management options for patients with HAE include:

- On-demand treatment to provide fast relief during episodes and treatments to help prevent episodes from occurring (prophylaxis).
- Short-term prophylaxis to help prevent symptoms in people with HAE who undergo dental or surgical procedures, which may trigger an attack.
- Long-term prophylaxis to help prevent episodes in patients whose quality of life is significantly impaired by the frequency and severity of attacks or by other factors related to the burden of HAE.

Guidelines recommend that assessment for access to long-term prophylaxis should consider a wide range of factors: disease activity, attack frequency, quality of life, availability of health-care resources, and failure to achieve adequate control with appropriate on-demand treatment. But there is no single assessment tool that includes all of these things and access to long-term prophylaxis is currently based only on HAE attack frequency.

To help improve this situation, the doctors involved in this study have developed a new questionnaire, called the HAE IMPACT PRO Tool. This questionnaire collects information from patients and uses this to calculate a score to determine the overall impact of their HAE. The purpose of this research is to test how well this new questionnaire works in patients with HAE so that in the future it might be used in HAE patients to assess their suitability for long-term prophylaxis therapy.

It is anticipated that 20 people who meet the eligibility criteria will be invited to participate in this research study.

Who is organising and funding the research?

This research is being sponsored by the patient organisation HAE Australasia Limited (ABN 34 152 887 440). HAE Australasia Limited has been provided with funding for this research from CSL Behring Australia Pty Ltd.

CSL Behring Australia Pty Ltd (ABN 48 160 734 761) may benefit financially from this research project if, for example, the project assists them to obtain approval for a change to the funding requirements for access to its HAE products. If knowledge acquired through this research project leads to discoveries that are of commercial value to CSL Behring Australia Pty Ltd, the researchers or their institutions, there will be no financial benefit to you or your family from these discoveries.

The study investigators will each receive an honorarium (personal financial benefit) to compensate them for their time involved in the analysis of the pooled, de-identified data collected from this research project.

The members of the research team are:

Principal Investigator:

- Professor Connie Katelaris,
  Consultant Allergy and Immunology Specialist, Allergy and Immunology Services, Westmead, NSW
  Professor Katelaris is on the Board of HAE Australasia; she is leading a group of doctors that has helped to design this research study.

Clinic specific investigator:

- Dr Raymond Mullins,
  Consultant Allergy and Immunology Specialist, Allergy Capital, Deakin ACT

Study administrator:

- Ms Hazel Palmer, Scriptix Pty Ltd (ABN 87 142 679 221)
  Scriptix Pty Ltd is a medical writing company; this company is being paid to conduct this research on behalf of HAE Australasia.

What does my participation in this research involve?

If you agree to participate in this research project, and sign the consent form, you will be sent an email giving you a personal link to access the study questionnaire on your computer.

The subject line of the email will be '**HAE IMPACT PRO Tool Questionnaire**'.

The study questionnaire will ask you for some background information:

- State of residence
- Current age (month and year of birth)
- Sex
- Date of diagnosis of HAE
- HAE-related medications list for last 6 months only

The study questionnaire will contain a series of questions about your HAE. These questions will include:

- the number and location of swelling episodes and the number of hospital visits related these episodes,
- the impact that your HAE has had on your mental, physical and emotional health, and on your work productivity.

These questions should take about 20 minutes to complete. You will only need to complete the questionnaire once.

The HAE IMPACT PRO Tool (questionnaire) does not collect identifying information such as your name, email address or IP address.

There are no therapeutic or clinical interventions in this research project. You will not be required to provide tissue samples or undergo any physical tests or procedures. No changes will be made to your medical care.

The answers that you provide to the questions will be used to calculate an HAE IMPACT SCORE. This HAE IMPACT SCORE will be used only for the purposes of this research and will not be retained in your medical records.

What are the possible benefits and harms of this study?

Participation in the study will not result in any immediate or direct benefit to you. The information you provide will help us to better understand how well the new HAE IMPACT PRO Tool works and to determine if it can be used in all HAE patients to assess their suitability for long-term prophylaxis therapy.

The main harm associated with this study is data harm/confidentiality breach.

For the purposes of this study, data will be collected and managed using a secure, web-based application that has been designed exclusively to support data capture for research studies.

The study sponsor will ensure an appropriate level of technical, administrative, and physical safeguards are used to protect the information you disclose by completing this online research survey. If you would like more information about these safeguards email the study administrator: hazel@scriptix.com.au

In the very unlikely event of data harm/confidentiality breach, the parties involved in this research project will do everything that they can to contain the breach and try to reduce the chance that the breach results in serious harm. If we determine that the breach is likely to result in serious harm, we will contact you and offer support.

Some of the questions in the survey ask about the impact that HAE is having on your life. The HAE Australasia website contains a number of tools and resources to help you with HAE related stress, anxiety and emotions. These resources can be accessed directly from:

- https://haeaustralasia.org.au/wp-content/uploads/2021/02/Living-Well-with-HAE-Empathy-Emotions.pdf
- https://haeaustralasia.org.au/wp-content/uploads/2021/02/Living-well-with-HAE-Stress-Anxiety.pdf

If you have any concerns about the potential mental health impact of completing this survey please discuss these with your doctor before you sign the consent form.

What are my rights and what happens if I change my mind?

Participation in this research project is entirely voluntary. You may refuse to participate in this research project or withdraw from it at any time. Your answers to the online survey will be automatically saved as you enter them. If you do decide to withdraw, any answers that you

have provided as part of the online survey ("information") up to that point will continue to be processed. If you do not want the researchers to do this, you must tell them as soon as you can after you have decided to withdraw.

To request that your information no longer be processed, email the study administrator: hazel@scriptix.com.au

What will happen to the information I provide?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential.

In the case of data that identifies you, or from which your identity may be ascertained, a person or organisation subject to Australian privacy laws that has collected your information must take reasonable steps to ensure that the information is handled in accordance with any relevant Australian privacy principle (unless an exemption applies). If you have any questions about this, direct them to the Principal Investigator.

Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. All information collected from you will be stored securely for a period of at least 5 years, and kept strictly confidential .

The HAE IMPACT SCORE, which is calculated from the answers you provide to the questionnaire, will be de-identified and combined with those of other study participants for analysis.

HAE Australasia Limited will own the study data. The information you provide will only be accessible by people that require access to it to carry out this research project. The information will only be shared with other researchers in a combined format (called "group data").

After analysis, the group data will be collated into a study report. This report will be sent to the study sponsor (HAE Australasia Limited) and any publications that result from this research will use only this study report.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

Are there any payments and costs?

You have been invited to participate in this study because you are a patient with HAE who is under the care of one of the study investigators.

There are no costs associated with participating in this research project, nor will you be paid.

Termination of the Study

The sponsor might decide to stop or suspend the study at its discretion and without having to advise the reason.

What will happen to the results from the study?

The information that you provide will be combined with other participants' information, this group data will be used to:

- Prepare a report to the sponsoring healthcare company.
- Prepare a publication so that the results will be available to other healthcare professionals to read.
- Prepare a plain language (lay) summary of the study results that will be made available to you upon request by emailing the study administrator: hazel@scriptix.com.au

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, only group data will be reported and published. This information will be provided in such a way that you cannot be identified, except with your permission.

Who can I contact if I have any questions about this study?

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this research project or if you have any questions, concerns or complaints about the research project at any stage, you can contact:

Name	Professor Connie Katelaris
Position	Principal Investigator
Telephone	(02) 9635 8060
Email	Connie.Katelaris@health.nsw.gov.au

If you want to withdraw from the research project at any stage, you can contact:

Name	Hazel Palmer
Position	Study Administrator
Telephone	(02) 9907 4593
Email	hazel@scriptix.com.au

Who has reviewed the research project?

The Bellberry Human Research Ethics Committee has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research (2007) incorporating all updates. This Statement has been developed to protect the interests of people who agree to participate in human research studies. Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved in the study, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Operations Manager, Bellberry Human Research Ethics Committee on 08 8361 3222.

Thank you for taking the time to consider this research project.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.
