

BSACI Registry for Immunotherapy (BRIT)

Patient Information Leaflet for Children 12 and Older in Scotland

You are being asked to be part of a research project called a 'patient registry'. Before deciding if you want to join, read this leaflet and ask your allergy doctor or nurse questions about it.

Who is BSACI?

BSACI stands for British Society for Allergy and Clinical Immunology. We are a group of scientists and health professionals who specialise in allergy. We want to improve how allergies are treated in the UK.

What is the BRIT Registry?

A patient registry, sometimes called a database, is a collection of information about people who have a certain condition or are getting a certain treatment. The BRIT registry is a collection of information about people being treated with immunotherapy for allergy. It helps us understand what kinds of treatments people are having and how well those treatments work. The aim of the registry is to find out what kinds of immunotherapy work best and for how long, so we can help provide better care in the future for people with allergy.

What will happen if I take part?

Information about your allergies and immunotherapy treatment will be stored in the registry. You will also be asked to complete some questionnaires that are like the ones your allergy doctor uses to monitor your how you're doing. We will send you (or your parent or guardian) an email or a text message every few months with a link to the questionnaire. When your treatment is finished, we will ask if you want us to continue sending the questionnaires so that we can find out how you are feeling over a longer period of time.

What information is kept in the registry?

The registry contains information that your allergy doctor collects during your appointments about you, your allergies, your treatments, and any side effects. It also contains your answers to the questionnaires we send.

Who will see my information?

The registry is owned by BSACI and only the people who work on the database will see the information. The registry is stored on a secure server which can only be accessed by certain approved people. Your allergy doctor and their

team will have access to it, but they cannot see any information about people they are not treating. Each person in the registry is given a unique number which does not identify them to anyone else. This number will be used whenever the data is viewed by anyone outside your allergy team or the BSACI so that no individuals in the registry can be identified. You can find more information about how we look after your data in our Privacy Notice, which your allergy doctor or nurse can show you and your parent or guardian.

What will happen to the data I provide?

Other people can ask to look at the registry's data. These can be either researchers or the companies that make the immunotherapy products. We will carefully review each of these requests and share only anonymous data.

Do I have to take part?

It is entirely up to you decide to take part in the registry. As a child over the age of 11 in Scotland, you will be asked to sign a form saying you want to participate (called a 'consent form'). You will also be asked to provide the personal information that you want us to include in the registry. If you don't want to join the registry, your treatment won't be impacted at all.

Can I change my mind later?

Yes. You can withdraw from the registry at any time without giving a reason. Any information held about you will be removed from the registry. In place will be a simple number showing that a patient has been removed. You are also allowed to ask us to remove parts of your data, such as your email address or any other details. If you want us to remove any or all your data from the registry, please contact

your allergy doctor or the registry administrator. Asking to be removed from the registry will not affect your care in any way.

If you want us to remove you from the registry, please tell your allergy doctor or email us at brit@bsaci.org.

Contact the Registry:

If you have questions about the registry and how it uses your data, phone or email the registry administrator.

Email: brit@bsaci.org

Phone: 0207 501 3919

Thank you for taking time to read this information sheet and for considering taking part in the registry.

If you have any questions or want any more information, please talk to your allergy doctor or a member of their team.

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Child Participant Registry Consent / Assent Form

Please read and write your initials next to each statement below.

Statement	Initials
I have read and understand the registry patient information leaflet. I have had time to think about the information and ask questions, and my questions have been answered.	
I understand that I am allowed to say 'no' to participating in the registry. If I do decide to participate, I am free to change my mind at any time, without giving any reason, and without my medical care or legal rights being affected. If I withdraw my consent, my information will be removed from the registry.	
I understand that information about me in the registry might be looked at by a small number of approved people from my hospital or allergy clinic or the NHS. I give permission for these few people to see my records.	
If I change allergy doctor or hospital during treatment, I agree to the transfer of my registry data to the new doctor. My record will still be visible to my previous doctor but it can only be changed or added to by the new doctor and their team.	
If I have completed (or will complete) a Participant Identifiers Form (the next section of this packet), I agree to the information I provide being held in the registry. I am aware that I can choose not to share that information.	
I understand information collected about me might be used to support other research in the future, but this information will be anonymous (which means personal information like name and birthday won't be shared). It may also be shared anonymously with certain approved people in the NHS. If I have a bad reaction, that information might be shared with the company that sells the medicine or researchers. All shared information will be anonymous.	
I agree for the Registry to contact me a) with questionnaires about my treatment: Yes <input type="checkbox"/> / No <input type="checkbox"/> b) with newsletters and updates about the registry: Yes <input type="checkbox"/> / No <input type="checkbox"/>	
I agree to take part in this registry.	

Please sign on reverse.

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Registry Consent for Children 12 and Older

Name of Participant (child):	Signature:	Date:
Name of Person Taking Consent:	Signature:	Date:

Name of Guardian:	
Signature:	Date:

**Please make one copy for the participant and file the original in the patient's medical notes.*

*BSACI **do not** require a copy of this consent form.*

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Participant Identifiers Form

To be completed by the participant or their parent / legal representative.

These details will be stored on the registry for access by your allergy doctor and their team.

First Name:	
Family Name:	
NHS Number (if known):	

Can we record your NHS number (CHI number in Scotland) in the registry? Yes / No

Your Contact Info:

We would like to send you or your parent or guardian some emails or text messages with questionnaires. The purpose of these questionnaires is to see how you're feeling and how well your treatment is working over time. We ask for your phone number because many people find it easier to complete these questionnaires through a text message link. You can opt out of receiving these questionnaires at any time.

Email Address:

Phone Number:

Can we contact you with questionnaires about your treatment?

Via Email: Yes / No

Via Text Message: Yes / No

Can we send you a monthly registry update to keep you informed about our progress (email only)? Yes / No

The following information will be used for analysis by the registry and is optional.

Date of Birth (DD/MM/YYYY):

**Date of Birth will be used to calculate your age age then removed from database*

What is your current gender identity?

- | | |
|--------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| <input type="checkbox"/> Male | <input type="checkbox"/> Female |
| <input type="checkbox"/> Transgender Male/Transgender Man/Female-to-Male (FTM) | <input type="checkbox"/> Transgender Female/Transgender Woman/Male-to-Female (MTF) |
| <input type="checkbox"/> Genderqueer/Non-Binary | <input type="checkbox"/> Additional Category (please specify): |
| <input type="checkbox"/> Choose not to disclose | _____ |

What sex were you assigned at birth on your original birth certificate?

- Male
 Female
 Choose not to say

Country of Residence:

<input type="checkbox"/> England (Greater London)	<input type="checkbox"/> Scotland
<input type="checkbox"/> England (outside London)	<input type="checkbox"/> Wales
<input type="checkbox"/> Northern Ireland	<input type="checkbox"/> Channel Island or Isle of Man
<input type="checkbox"/> Other (please specify):	_____

Home Postcode:

**Your postcode will be used to calculate the distance from your home to your allergy clinic and then it will be removed from analysis. You can give only the first part if you prefer, such as W2 or SO16.*

Please circle your ethnicity code from the list below.

A. White

1	English / Welsh / Scottish / Northern Irish / British
2	Irish
3	Gypsy or Irish Traveller
4	Any other White background (please write):

B. Mixed / Multiple Ethnic Groups

5	White and Black Caribbean
6	White and Black African
7	White and Asian
8	Any other Mixed / Multiple Ethnic background (please write):

C. Asian / Asian British / Asian Irish

9	Indian
10	Pakistani
11	Bangladeshi
12	Chinese
13	Any other Asian background (please write):

D. Black / African / Caribbean / Black British / Black Irish

14	African
15	Caribbean
16	Any other Black / African / Caribbean background (please write):

E. Other Ethnic Group

17	Arab
18	Any other ethnic group (please write):

*Coding for Ethnic Group is based on Office for National Statistics 2011 for UK wide data collection.

Thank you for completing this questionnaire. Please return it to your immunotherapy doctor or nurse.

This form should be filed in the medical notes once data has been entered in the Registry.

BRIT does not need a copy.