



## BSACI Registry for Immunotherapy (BRIT)

*You are being invited to take part in a patient registry for people receiving immunotherapy for allergies and urticaria. Before you decide whether you should take part, it is important that you understand why this project is taking place and what it will involve.*

*Please take time to read the following information carefully and talk to others about it if you want to. You can also ask the doctors and nurses looking after you if there is anything that you do not understand or if you would like any more information. Take time to decide if you wish you to take part in this project.*

### **What is the BRIT Registry?**

A patient registry is a database or collection of information about people affected by a disease, or having a specific treatment or operation. BRIT is a registry for people being treated with immunotherapy. It is held on a secure internet based database. BRIT keeps track of what treatment has been prescribed and any side effects or reactions from these medicines.

The data from the Registry will be used to help develop specialist immunotherapy around the UK and to review the safety and effectiveness of these medicines.

### **What will happen if I take part?**

Your data will be uploaded by your team and if you have agreed to be included in emails, you will start to receive emails from the Registry. These will occur at regular intervals and ask you to complete an online questionnaire. Many immunotherapy centres use paper questionnaires to monitor treatment, the online questionnaires will be very similar. We will also send newsletters and updates about the Registry.

Many forms of immunotherapy continue to provide benefit for a period after they have been stopped. This can be months, years or even lifelong in some cases, depending upon what treatment has been given. Ask your specialist about what you might expect from your treatment. Once your treatment has finished, we will ask you if you would like to continue to receive emails. This will help to monitor the long-term effectiveness of these treatments.

### **Why have an Immunotherapy Registry?**

Immunotherapy for tree, grass, venom, house dust mite, animal and peanut allergy is a highly specialised treatment. The registry will record the number of people in the UK on immunotherapy and where they are being

treated. It will also show how treatments are working and what side effects can be expected. It will help to provide better care for people with allergies in the future. It will also help your consultant to maintain best practice, and will show how access to these specialist treatments varies around the country.

### **What information is kept in the Registry?**

The information kept in the Registry is like the information that is recorded during visits to Clinic. It will include information that might identify you to others. We will ask you to complete a form with these identifiers – so that you know exactly what is being included. It also includes details about allergies, the type of treatment and if the treatment was a success, based on the online questionnaires that you complete. It also lists any side effects from the medication that you or your doctor have reported.

### **Do I have to take part?**

It is up to you decide to take part in the Registry. You will be asked to sign a consent form and the personal information that you wish to be included in the Registry. Your care will not be affected in any way if you decide not to take part.

### **Can I change my mind later?**

You can unsubscribe from Registry emails at any time. We will keep your Registry record entry on file in line with current UK law and then it will be deleted.

You are also able to opt out and withdraw from the Registry at any time without giving a reason. Any information held about you will be removed from the Registry. If you want to opt out, please contact your local clinician or email or the register administrator, [brit@bsaci.org](mailto:brit@bsaci.org). Choosing to opt out of the Registry will not affect the quality of your care in any way.

### **Will my information be kept confidential?**

The BSACI is the professional society for Allergy specialists and Clinical Immunologists in the UK. The data on the Registry is owned by BSACI and managed by the Registry Steering Committee, which is made up of specialist doctors and nurses and patient representatives from the Anaphylaxis Campaign and Allergy UK.

BSACI control the data and most analysis will be undertaken by specialists of the Registry Steering Committee. Only anonymous data will be downloaded for analysis by the RSC.

All the information in the Registry is held on secure internet servers behind an NHS firewall. It is managed in accordance with relevant data protection laws and ethical principles. The Registry is managed by Dendrite Clinical Systems.

Only a few people will have access to the identifiable information stored about you in this Registry. Your consultant specialist and their clinical team will have access to the personal information stored about you, so that they can easily update your records and see how treatment is working.

A very small number of experienced administration staff at BSACI (these are referred to as 'trusted third parties') will also be able to see your personal information. This is to enable the information to be updated or deleted if you want to opt out, and to keep the system maintained in accordance with data protection laws.

Each Registry participant will be given a unique number which does not identify them to others. This number will be used when the Registry data is analysed by the BSACI.

The Registry has been paid for by some of the companies who provide immunotherapy

treatments but they do not control or own the data.

### **What will happen to the data?**

Other researchers in the UK and abroad may also request to use this important dataset. The RSC will review requests by the regulatory authorities, researchers and pharmaceutical companies to use the data collected by the Registry. Only anonymous data will be downloaded for these purposes.

Further information about how we handle your personal information is available in our **Privacy Notice**. Ask your consultant specialist for a copy or contact the Registry.

### **How to contact the Registry**

If you have any questions about the use of your data or you want your information removed or updated, please contact the registry administrator by email [brit@bsaci.org](mailto:brit@bsaci.org) or 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 require any further information, please talk to a member of the care team at your Allergy Clinic.





## BSACI Registry for Immunotherapy (BRIT)

### Participant Registry Consent Form

| Statement  | Initials |
|--|----------|
| I confirm that I have read and understand the Registry participant information sheet dated 1st October 2018 (Version 1.0). I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.   |          |
| I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.   |          |
| I understand that information about me collected from my medical notes and the registry may be looked at by a small number of responsible individuals from the NHS Trust / Private Hospital or the regulatory authorities. I give permission for these individuals to have access to my records  |          |
| If I change consultant or hospital during treatment I agree to the transfer of my registry data to the new consultant. (My record will still be visible to my previous consultant but will only be active for the new consultant and their team.)  |          |
| I have completed a Participant Identifiers Form (Version 1.1 Dated 16th October 2018). I agree to this personal identifiable information being held by the registry. (You can also choose not to provide this information if you prefer.)  |          |
| I understand that non-identifiable information collected about me may be used to support other research in the future and may be shared anonymously with the regulatory authorities and the pharmaceutical company that holds the Marketing Authorisation for the UK in the event of an adverse reaction, or with researchers in the UK or abroad. |          |
| I agree for the Registry to contact me to<br>a) see if my treatment is working: Yes <input type="checkbox"/> / No <input type="checkbox"/><br>b) send me 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.**

|                                |            |       |
|--------------------------------|------------|-------|
| Name of Patient:               | Signature: | Date: |
| Name of Person Taking Consent: | Signature: | Date: |

One copy for the Participant, original to be filed in medical notes.

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



## BSACI Registry for Immunotherapy (BRIT)

### 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 consultant and their team.

|              |  |
|--------------|--|
| First Name:  |  |
| Family Name: |  |
| NHS Number:  |  |

Can we record your NHS number in the registry? Yes  / No

(In Scotland: No need to record CHI number, we can get it from your records)

#### Your Contact Info:

*We would like to contact you by email and SMS to see how treatment is working.*

*We would also like to send you email updates from the registry so that you can see the work we are doing.*

#### Your Email Address:

#### Your Phone Number:

Can we contact you to ask how your treatment is going? Yes  / No

Can we send you newsletters and registry updates? Yes  / No

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

Date of Birth (DD/MM/YYYY):

|  |
|--|
|  |
|--|

*\*DOB will be used to calculate age then removed from database*

Gender:

|                                 |                               |  |
|---------------------------------|-------------------------------|--|
| Female <input type="checkbox"/> | Male <input type="checkbox"/> | Prefer not to say <input type="checkbox"/> |
|---------------------------------|-------------------------------|--|

Gender Identity:

|                                |                                    |  |
|--------------------------------|------------------------------------|--|
| Birth <input type="checkbox"/> | Non-Birth <input type="checkbox"/> | Prefer not to say <input type="checkbox"/> |
|--------------------------------|------------------------------------|--|

Occupation (if over 16 years old):

|  |
|--|
|  |
|--|

Country of Residence:

|   |  |
|---|--|
| England <input type="checkbox"/>          | Scotland <input type="checkbox"/>                      |
| Ireland <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 clinic and generate sociodemographic codes. The postcode will then be removed from analysis. You can give only the first part if you prefer, e.g. 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.