BSACI Registry for Immunotherapy (BRIT)

BSACI
Improving Allergy Care
through education, training and research

What is BRIT?

BRIT is a web-based patient registry open to all BSACI consultants treating patients with immunotherapy. You can include patients on pollen, house dust mite, animal dander, venom and peanut immunotherapy, as well as Omalizumab (Xolair) for chronic spontaneous urticaria. It has been designed for both adult and paediatric patients seen either in the NHS or in private practice. The registry will contact patients regularly to complete short online questionnaires, both during and after treatment as long term follow up.

The objectives of the registry are:

1. To describe the use of immunotherapy in the UK in adults and children.
2. To describe the safety and effectiveness of immunotherapy, both during and after treatment.
3. To benchmark clinical practice within the BSACI registry membership to improve standards of care and describe access to services nationally.

Why should I get involved?

By using the registry, you will have a patient's response to treatment available at a glance. Once consented and enrolled, an individual patient's response to treatment is collected automatically by text/email, and can be viewed on their timeline summary in the Registry. This makes BRIT a useful tool to have on your desktop in clinical practice.

It will also help with safety reporting to MHRA Yellow Card scheme and the Pharmaceutical Industry in line with best practice in pharmacovigilance. This is important as many of the products that we use are not licensed in the UK.

BRIT is also an opportunity for clinicians to be actively involved in establishing immunotherapy as a specialist treatment in the UK. Using the Registry can contribute towards your IQAS accreditation and will bench mark your practice in line with current BSACI guidelines.

Because individual consultants have access to data from across their centre, registering with BRIT is beneficial for auditing purposes, and is recommended by IQAS for service accreditation.

What data will be collected?

The registry collects data regarding patient episodes of treatment (rather than individual visits). It uses current BSACI guidelines to benchmark your practice. Effectiveness will be determined by Quality of Life questionnaires sent to patients (parents/guardians in case of children) by email regularly during treatment and, if they consent, as long term follow up after treatment has finished. You will also be able to report serious adverse events, and other adverse reactions leading to discontinuation of treatment.

How does BRIT protect data?

BRIT is held on secure servers within the NHS. The registry is managed by Dendrite Clinical Systems Ltd., who has many years of experience in hosting similar national and international registries. BRIT contains both identifiable and non-identifiable participant data. All participants must have signed informed consent before their data can be entered into the registry. To view a copy of our Data Protection Impact Assessment, email **brit@bsaci.org**.

Who has access to the data?

Individual consultants have access to their own participant's data. The central BSACI Registry administrator also has access to participant identifiable information so that individuals' data can be kept up to date or removed in line with data protection regulations.

The registry steering committee (RSC) oversees the running of the registry. The data is owned by BSACI, not the NHS nor the funders or web-host. The RSC is made up of BSACI members and has patient group representatives from the Anaphylaxis Campaign and Allergy UK. The RSC is independent of the funders and reports directly to the BSACI Council.

The RSC does not have access to individual participant identifiable information but can use the non-identifiable dataset for data analysis and dissemination of the results.

The RSC also reviews applications to use Registry data for research purposes from organisations outside of BSACI, but this is confined to non-identifiable data and is not commercially sensitive.

Ethical Approval

BRIT is a Registry Database and as such does not need Research Ethics Committee approval. All individuals whose data are recorded on the database will need to have signed informed consent. They are allowed to withdraw whenever they wish. Further consent is required once treatment has finished for long term follow up.

How is BRIT funded?

BRIT has been established by grant funding from the Pharmaceutical industry. Aimmune, ALK Abello, Allergy Therapeutics and Thermo Fisher are funding further development of the Registry. These companies have no role in the running of the registry. BSACI remains the owners of the data.

How do I join?

BRIT is open to all consultants (or equivalent grade practitioners) who are members of BSACI.

To register, visit www.bsaci.org or contact the registry coordinator