bsaci
improving allergy care
through education, training and research

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# BSACI Registry for Immunotherapy

## Getting started with BRIT – Information for new users

BRIT is a powerful web-based database for patients treated with immunotherapy. There is a learning curve to get used to the system. We hope that this leaflet will guide you through the database, show you around the project, give tips on how to get started and recruit your first participant, and learn how to use the BRIT to help you in your clinical practice

### What's BRIT all about

You can include patients receiving pollen, house dust mite, animal dander, by both subcut and sublingual routes, venom immunotherapy to bee or wasp stings and also the use of Omalizumab (Xolair) for chronic spontaneous urticaria.

The objectives of the registry are to:

1. To prospectively describe the use of immunotherapy in the UK in adults and children.
2. To prospectively 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.

### Consultant users

The registry is open to all BSACI members who are consultant grade or equivalent such as nurse consultants or consultant grade pharmacists. It is a benefit of membership. Consultants will frequently work across several hospitals in both in the NHS and private practice. The registry allows consultants to record patients from different hospitals and practices under one account.

Register at http://brit.e-dendrite.com/

### Can non-consultants use the registry?

Consultants can enrol delegate users from their clinical team to help with data collection and recruitment. Delegates need the express permission from the consultant to work on their behalf. Delegate users include junior doctors, nurse specialist or medical secretary and would be part of the direct care team. Delegate users should also register at http://brit.e-dendrite.com/.

### Consultants working in teams

You can share data between consultants working in the same practice. Simply contact the registry (registry@bsaci.org) with the names of the consultants you wish to share and we can grant access to your patients to the other consultants in your team. In this way consultant's can be delegated users for each other at the same practice. This reflects how most allergists work.

### Consultants working abroad

The registry is not available for BSACI consultant members who practice outside of the UK. The ethical and data protection framework is based on UK law and will not apply outside of these borders.

### Principles of BRIT

There are three overriding principles is that govern the management of this registry:
1) **We work in partnership with our patients.** Data is only collected with the express consent of the participant. We rely on them for long term follow up of their outcomes to help us and others like them. Allergy UK and the Anaphylaxis Campaign

support this project and are permanent members of the Steering Committee.
2) **We work in partnership with the healthcare users of the database.** The registry should be useful for all users and participants. The data that you put in easily accessed so that you can get it back out again as spreadsheets summarising your service. So you can get our what you put in at the click of a button. This will help with local audit and service evaluation. We will establish a **super users' forum** for users with many participants. So that you can help to guide the development and analysis of the larger dataset.
3) **We only collect data where it serves a purpose**. We do not ask for data without a good reason for doing so, for instance to show compliance with current BSACI guidelines. This keeps the database as lean as possible and makes clinically relevant to enter new data. The data required for each part of the registry can be found as pdf form to print and use in clinic from the **Download** area of the Registry.

## Ethics

The registry is a type of project known as a registry database by the Health Research Authority[1]. As such BRIT does not require ethical approval to collect data. However, we will seek ethical approval for secondary and research hypothesis driven analysis of the data set, once the Registry is up and running.

## Data protection and GDPR

BRIT is GDPR compliant. BSACI processes participant data with their express written consent and handles only the identifiers that they choose to share. The Registry collects patient identifiable information with the express consent of the participants. This allows easy recognition of the patients by the clinical team and the demographics will inform our understanding of access to specialist services. Names and NHS numbers are not shared outside the clinical team of the consultant. They can only be seen by those people directly involved in their clinical care and the administrative user at the BSACI who needs access to keep patient's records up-to-date in line with current data protection regulations. More information on GDPR compliance can be found in **BRIT Privacy Notice** (fair processing) the Download area of the Registry. It should be shared with patients that have further questions about the security of their data.

## Online security of the database

The Registry is stored in secure N3 Carelink servers within the NHS but can be accessed from any computer both within the NHS and outside of the NHS. The Registry is managed by Dendrite Clinical Systems Ltd, who has many years of experience in hosting similar national and international clinical registries.

## Structure of the Registry

There is a central participant registration page followed by basic demographic details. From there the registration will vary according to which immunotherapy modality is being prescribed, AIT, VIT or OMA. PROM can be entered manually from the Timeline page for that participant or directly by the patient with online reporting. Adverse reactions can also be entered from the Timeline page.

The data required for each part of the registry can be found as pdf form to print and use in clinic from the **Download** area of the Registry.

## Adding a new participant

The database is organised to make adding new patient as simple as possible. Immunotherapy is described by courses rather than by injections. For instance someone starting subcutaneous grass pollen therapy will be included as a new patient at their first injection and no further additions to the database are required until the course is complete. This may be several years later.

## Is BRIT for new patients only?

The Registry can include new and current patients receiving immunotherapy.

[1] https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-tissue-banks-and-research-databases/

Similarly, the patient half way through bee venom immunotherapy will be entered once consented and the date of first injection at the initial course injection added retrospectively, with no further changes until discontinued (normally three years 3 to 5 years later).

## Automated patient reported outcomes

Once admitted the patient will be enrolled into the electronic **patient reported outcome measures** scheme. They will receive emails at regular intervals that ask them to complete online questionnaires from the registry. The frequency and type of questionnaires will vary according to immunotherapy regime. Patient related outcomes can also be entered manually into the registry by the care team users. This is useful if they routinely complete paper based questionnaires in your clinic or you use in additional measures to track the outcome of your patients. You can add your bespoke scores to the system.

**Electronic reporting has not launched yet but should do so before Christmas 2018.** Please enter PROM manually for now.

## Long term follow up

At the end of treatment your patient will receive an email asking them to enrol in long term follow up. They will then receive regular emails from the Registry until they choose to unsubscribe. We hope in this way BRIT will be able to gather data on the long-term outcomes of our patients' years after we have discharged from allergy clinic.

## Making clinic easier

Patient reported outcomes are visible on the **Timeline** screen for each patient on the registry. This makes it easy to track the progress of a registry participant and their response to treatment. We hope that the timeline screen will become a key part of your clinical assessment that will help you in providing appropriate treatment for your patients.

## Adverse reactions

BRIT will also make your practice safer. You can also enter adverse reactions from immunotherapy treatment. We do not expect you to report all side-effects of treatment, only those that will lead to significant alteration in dosage or discontinuation of immunotherapy. There is a **safety tracker** within the registry that will alert the Registry Steering Committee to any serious adverse events reported to BRIT.

An RSC consultant will contact their lead consultant in order to assist with Pharmacovigillance reporting, such as to the MHRA yellow Card system. (The registry can generate an AR report for this purpose). This is an important safety feature as it will alert the Allergy community in the UK to serious reactions occurring from treatment. It will play an important role in Pharmacovigilance and provide confidence to patients and commissioners regarding our treatment.

## How to enrol your first patient

Participants must sign a consent form and complete the personal identifiers questionnaire before data can be uploaded to the registry. There are a range of consent forms and patient information leaflet available for download from the registry **Download documents** area.

There are a range of **patient information leaflets** available to inform their choices. BSACI do not need copies of these consent forms. We have **consent forms** for adults 16 years and older, for parents of children under 16 years of age. We also have a consent form for children living in Scotland between the ages 12 and 15 who are able to sign their own consent with parental assent. Participants should also complete a **Participant identifier form** to accompany the consent document.

Signed consent and the identifier form should be filed in the patient's notes once completed so that they are easily retrieved for audit and regulatory purposes.

## What does the colour coded homepage mean?

All participants under your care are listed on the homepage and the entry is given a background colour. This includes patients where you are lead consultant and those where you are a delegated user by another consultant.

Green – consent in place on active treatment

Yellow – consent in place under follow up

Red - no consent on file, this will change when a child becomes 16 where adult consent should to be sought to replace the parental consent.

## Where to start

We suggest that you start small and work up. Recruit one participant each clinic to start with until you get used to the system and the flow of the process. It should take less than five minutes to register a new participant once you get used to the system.

## Other resources

There is a pdf user guide with screen shots and the data required for each part of the registry can be found as pdf form to print and use in clinic from the **Download** area of the Registry.

## Contact us

Data entry queries and password reset: national-support@e-dendrite.com
Registration queries: registry@bsaci.org
Bugs and fixes: registry@bsaci.org
Development ideas: brit@bsaci.org
Super user forums: brit@bsaci.org

## Thanks!

We hope that being part of the registry will become a mark of good practice and that you will find it useful in the clinical management of your patients.

Dr Mich Lajeunesse
On behalf of the Registry Steering Committee