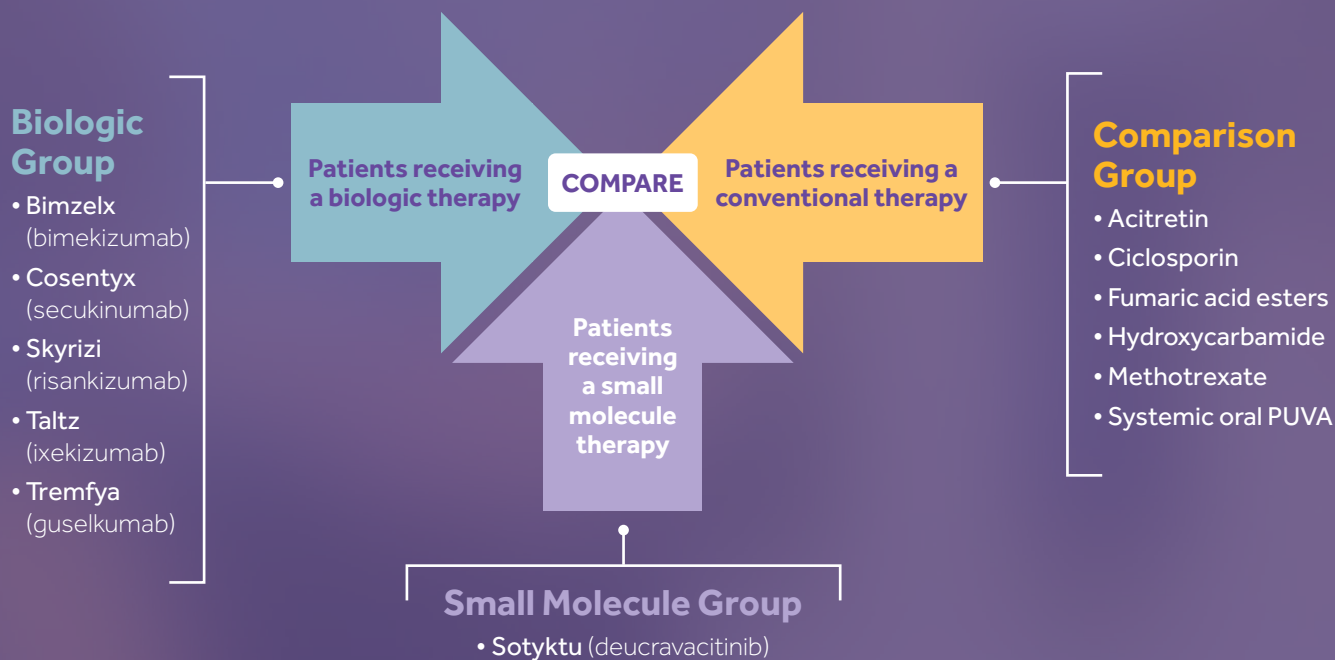


Welcome

The British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR) is a drug safety register seeking to assess the long-term safety of treatments for psoriasis in a real world population.

Once patients have joined BADBIR, their dermatologist provides information to BADBIR for us to carry out research into the safety and effectiveness of their treatments. In this newsletter you can read more about how this works and our recent publications.

To assess safety, BADBIR compares the experience of patients receiving different types of psoriasis treatment



If you have recently started on a treatment shown you may be eligible to join BADBIR. If you are interested please speak to your Dermatologist who will provide you with more information. We have data collected for 32 different psoriasis treatments and this continues to grow as new treatments become available.

The purpose of BADBIR

Drugs have been carefully tested for safety in clinical trials. However these trials are:

- Run for a relatively short period of time
- Have limited numbers of participants
- May exclude people with additional diseases (co-morbidities)

BADBIR was established to assess the long term safety of newer drugs by following a real world population of people with psoriasis from all areas of the UK and Republic of Ireland.

Collecting your data



When you join BADBIR, as well as the questionnaires you complete, the following information will be collected:

- Your demographic data (name, age, gender, hospital number)
- The current severity of your psoriasis
- Psoriasis treatments past and current
- Your overall health
- Current medications

When you are registered with BADBIR, at each follow-up your clinician will update us on:

- The treatments you receive for your psoriasis
- An update on any other medications you take
- Assessments of your psoriasis disease severity
- Details of any illnesses or adverse events you have suffered

As well as the treatments you take for your psoriasis it is also important that we take into consideration your overall health and other medications. This will help

researchers determine if any of the ill effects you might encounter are linked to the medications you are taking for other conditions, or if they are from your psoriasis treatment.

In addition to collecting data directly from your clinician, the BADBIR study links to a number of national healthcare data providers to collect additional information. Once you have consented to join BADBIR, a link can be established to the relevant national provider.

This link will provide a comprehensive data collection method to ensure we do not miss any important safety data.

Your identifiable data will not be shared with anyone else aside from the linkage services as part of their routine flagging process.

The pharmaceutical companies who manufacture the treatments you receive will have access to some study data, this data will not include any information which you may be identified by (name, hospital numbers etc.) These companies receive this data so that they can update records with the international regulatory government agencies responsible for drug safety.

Key statistics

Thank you to the

21,318

patients who take part in BADBIR



99,766

Adverse events entered

(Any medical occurrences during patients' time on BADBIR)



194,967

PASIs collected

(A score to measure of the severity of your psoriasis)



94,611

DLQIs completed

(Your quality of life questionnaire)



141,167

follow-up visits have been completed



37

Journal Articles Published Using Data from BADBIR

Data held on

34

Different Systemic Treatments for Psoriasis

Young People in BADBIR



Psoriasis is not uncommon in children: one third of adult patients start their journey in childhood and 10% of patients with chronic plaque psoriasis present before the age of 10.

Childhood psoriasis can influence all aspects of a young person's daily life, and there can sometimes be lasting impacts into adolescence and later life.

Over the past decade treatment options are rapidly expanding and there is a need for better guidance on what to use, when and how.

A real need persists for real world data, longer term follow-up for all medications.

Previously, young people may not have have been treated with tablet or injectable medications. This is now changing and there is a move to provide a more effective control for their psoriasis. As these treatments become more frequent, the need for young people to be included in BADBIR becomes even more urgent. Their data will allow analysis to take place in order for us to understand the risks and benefits of these treatments in younger patients.

If your child has started a new systemic treatment for their psoriasis in the last 6 months and you would like them to participate in BADBIR please speak to your clinician who will provide you with more information.

Publication summaries



There are currently 37 published articles using BADBIR data. The analysis of this data has also contributed to many posters and presentations at conferences across the globe.

It is your participation in BADBIR which allows the register to provide a wealth of information to our healthcare professionals.

Here is a summary of recent publications using BADBIR data. If you would like to read these articles in full, you can visit www.badbir.org to find links to all publications.

Genetic risk in psoriasis patients developing eczema after biologic therapy

It was found that people with psoriasis who developed eczema after treatment with biologics were likely to have a genetic tendency to atopic diseases. Atopic diseases include atopic eczema, asthma and hay fever. This was found to be true even if the person did not suffer from any of these atopic diseases in the past.

Conclusion

This confirms that genetic risk is one of the factors contributing to the occurrence of eczema in some people with psoriasis receiving biologics.

How effective are biologic therapies in improving the quality of life in patients with psoriasis?

- Three biologic treatments were researched: Humira, Enbrel and Stelara. All three improved the quality of life of those receiving the treatments over the first year, this was made evident from the improved scores from two patient questionnaires: Dermatology Life Quality Index (DLQI) and EuroQoL which is a measurement of health-related quality of life.
- The biggest improvement was in the pain/discomfort area.

We found that the following factors were less likely to show greater improvements in the quality of life in patients receiving Enbrel compared to Humira:

- Females
- Current smokers
- Obese patients
- Patients with multiple medical conditions

Conclusion

We found that biologic therapies improved the quality of life for people with psoriasis and that it is influenced by

- The choice of biologic therapy
- Lifestyle characteristics (e.g. obesity and smoking)
- Other medical conditions.

Lifestyle changes, including quitting smoking and weight loss for obese patients, may improve the effectiveness of biologic therapies.

Effectiveness of methotrexate versus adalimumab in patients with moderate-to-severe psoriasis

Treatment effectiveness was defined as achieving clear or almost clear skin and survival as the time between the start and the discontinuation of treatment associated with ineffectiveness or occurrence of adverse events.

A total of 6,575 psoriasis patients were included in the analysis, of whom 3,916 (60%) were on adalimumab and 2,659 (40%) on methotrexate at enrolment. We found that the proportion of patients achieving clear or almost clear skin was higher in the adalimumab cohort (77%) compared with methotrexate (37%). We showed that patients would stop methotrexate 6 months sooner than those on adalimumab.

Conclusion

Patients on adalimumab were twice as likely to be clear or nearly clear of psoriasis and were less likely to discontinue their medication as compared to patients on methotrexate. Findings from this real-world cohort provide important information to aid clinicians managing psoriasis patients.

The real-world effectiveness and persistence of acitretin, ciclosporin, fumaric acid esters and methotrexate for treating moderate-to-severe psoriasis

We found that these treatments are only effective in up to one-third of people to achieve clear or almost clear skin. People would continue to take methotrexate for longer compared with acitretin, ciclosporin and fumaric acid esters.

Conclusion

The real-world effectiveness and persistence of acitretin, ciclosporin, fumaric acid esters and methotrexate were generally low. Previous non-biologic (tablet) systemic therapies, male sex, other health problems and alcohol consumption were associated with a poorer response to treatment. Findings from this study provide important information to aid clinicians and their patients when managing psoriasis with non-biologic therapies include acitretin, ciclosporin, fumaric acid esters and methotrexate.

Application of artificial intelligence to predict effective biologic treatment options for patients

Studies using BADBIR data have shown that biologics are highly effective drugs to treat moderate to severe psoriasis. However, these studies have also highlighted that a proportion of people do switch biologic therapy, due to lack of effectiveness or adverse events.

For clinicians, there is currently no good evidence-base to guide biologic treatment selection. Application of artificial intelligence could allow clinicians to choose the most safe and effective drug for an individual patient.

Conclusion

This research demonstrated that artificial intelligence can be successfully applied to BADBIR data and this could be useful to select treatment for people with psoriasis in the future.

Publication summaries



What is the risk of major cardiovascular events in people with psoriasis receiving biologic therapies?

We investigated whether people receiving Stelara, Humira, Enbrel or methotrexate had different risks of developing a new cardiovascular events, including heart attack and stroke.

Conclusion

We found no differences in the rates of new cases of cardiovascular events between the therapies, reassuring us that we don't have any evidence that these therapies increase the risk.

Is there a risk of serious infection in patients with psoriasis receiving biologics?

People receiving Humira, Enbrel and Stelara did not have a significantly higher risk of serious infections as compared to the control group. There was also no difference in the risk of serious infections between Humira, Enbrel and Stelara.

Conclusion

The risk of serious infection should not be a primary concern for patients and clinicians when deciding between these treatment options.

Tumour Necrosis Factor Inhibitors (TNFi) are effective but costly treatments for moderate to severe psoriasis

Tumour Necrosis Factor Inhibitors (TNFi) are a type of biologic drug, they were amongst the first biologic agents prescribed for psoriasis in the UK. Biosimilars are developed from the original biologic agents, they are highly similar to licensed originator compounds, are much cheaper and therefore offer potential cost savings in healthcare. Our objective is to describe the biosimilar distribution in psoriasis treatment in the UK and the Republic of Ireland.

Conclusion

Our study found that over time, more people using the original biologics switched to biosimilars. However, the use of biosimilars varied in different regions of the UK and the Republic of Ireland.

Future Work

Assessing biosimilars' long-term effectiveness and safety in real-world settings by looking at how likely people are to stop using these treatments can inform clinical decision-making and identify optimal treatment options. Evaluating the risk of adverse events associated with biosimilars in real-world settings is also crucial as it may differ from clinical trial estimates.

Interested to know more?

For further details on BADBIR publications and upcoming work please visit the website

www.badbir.org/publications

A big thank you to all participants!

By participating, you are helping us build up the amount of data we have for analysis. With more data, we will be able to reach better-informed conclusions on the long-term safety of biologic treatments.

The feedback from patients say that they feel good helping in research, and this for us is extremely rewarding.

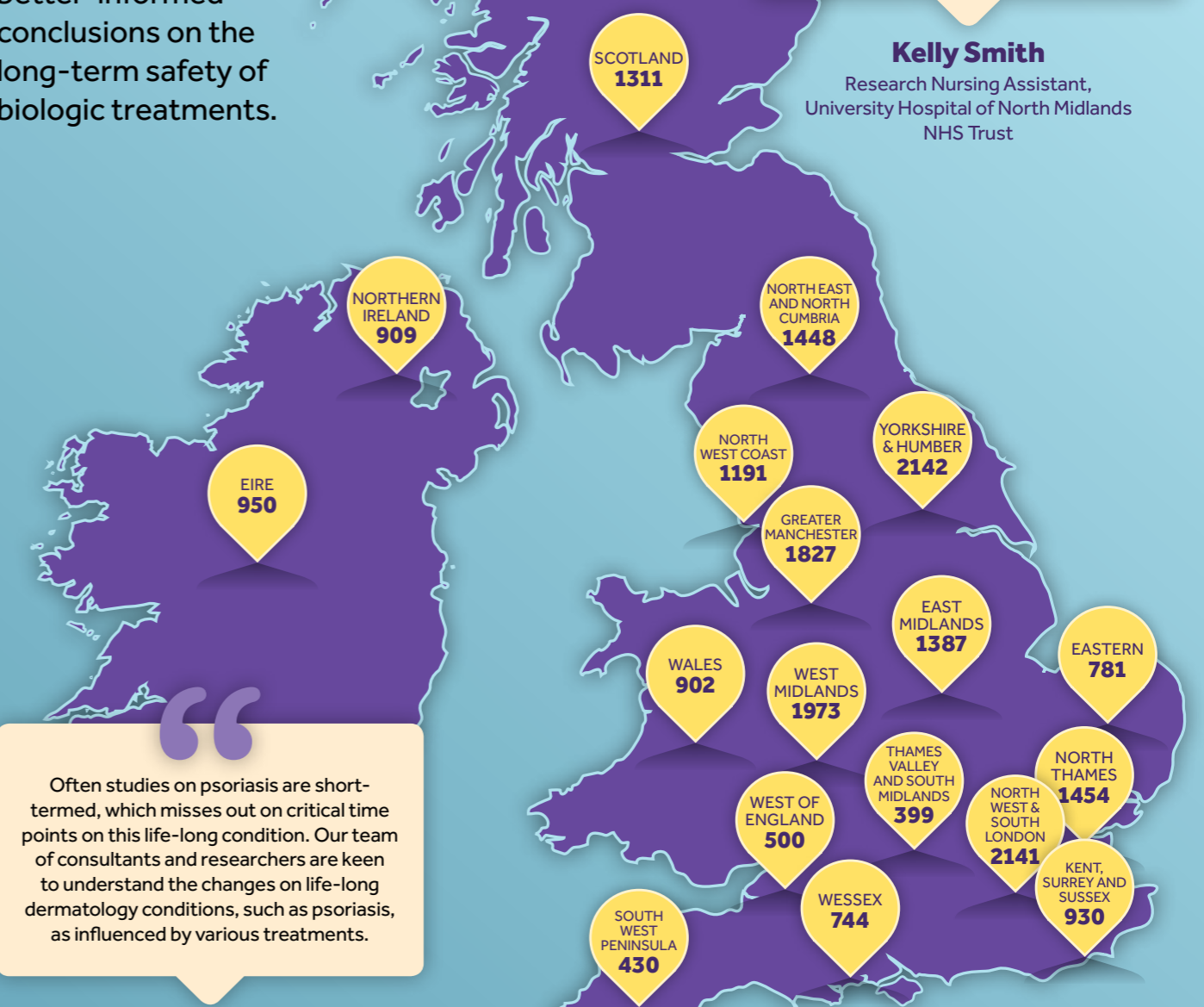
Wendlyn Bell

Clinical Trial Associate, Newcastle Upon Tyne Hospitals NHS Foundation Trust

We feel passionate about delivering an accurate account of the patient outcomes and ensuring that the suitable patients are successfully protected and cared for.

Kelly Smith

Research Nursing Assistant, University Hospital of North Midlands NHS Trust



Often studies on psoriasis are short-termed, which misses out on critical time points on this life-long condition. Our team of consultants and researchers are keen to understand the changes on life-long dermatology conditions, such as psoriasis, as influenced by various treatments.

Ikenna C Ohanenye

Clinical Research Practitioner, Royal Free London NHS Trust (Barnet Hospital)

Map illustrating patient registrations across the United Kingdom and Republic of Ireland.

You can help by going online!

We have introduced the Patient Portal to provide another method for you to complete questionnaires. Previously, we have only asked you to complete the questionnaires on paper when you've attended a dermatology clinic appointment.

We have created the Patient Portal so that the questionnaires can be completed easily from your phone, tablet or computer.

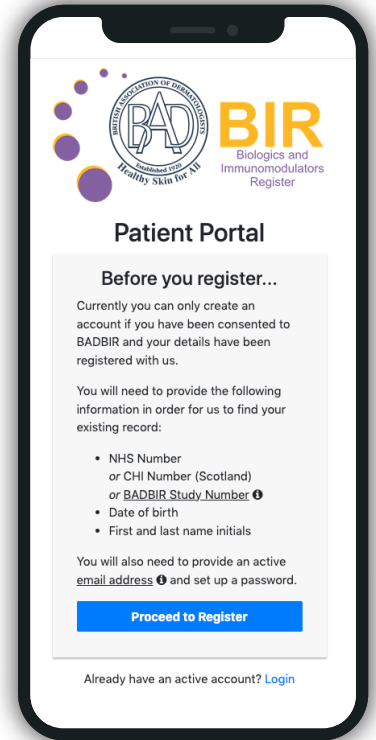
- **Saves time in clinic**
- **Reduces waiting time**
- **Reduces work load for hospital staff-**
- **Removes the need for hospital staff to enter your questionnaires on the database**
- **Go green—save paper, printing and scanning costs**

You can access the Portal via the BADBIR website www.badbir.org

You will need:

- England and Wales and Northern Ireland
NHS Number
- Scotland
CHI Number
- Republic of Ireland
BADBIR study ID
- Date of Birth
- First and Last name initials

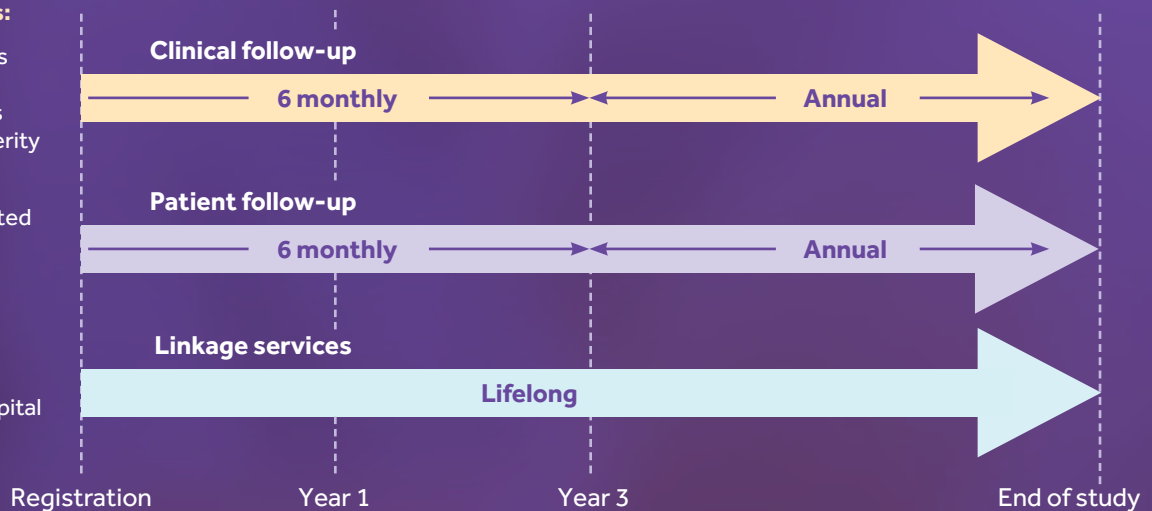
Once you have registered with the Patient Portal we will send you an email when your questionnaires are required, which will normally be every 6 months until you have been on the register for 3 years and then it will continue annually until the end of the study.



Summary of the information collected

Data collected on Medical histories:

- Comorbidities
- Drug details
- Safety events
- Psoriasis severity
- Patient reported measures
- Lifestyle
- Cancers
- Deaths
- Inpatient hospital admissions



For queries on any aspect of BADBIR

DW.3800.09.23

email: badbir@manchester.ac.uk

www.badbir.org

[@BADBIR](https://twitter.com/BADBIR)