

Welcome to the 2nd edition of the British Association of Dermatologists Biologic Interventions Register (BADBIR) study patient newsletter. Here are some news updates since our first edition in 2016:

- 156 centres** are now recruiting patients to BADBIR
- Three new research papers** using BADBIR data have been published in 2017 so far
- Taltz (ixekizumab)**, a new biologic, was approved for use in psoriasis. BADBIR is recruiting patients starting or switching to Taltz
- Over 2,000 new registrations** have been added to BADBIR

Who are we?
 BADBIR is a drug safety register interested in studying the long term safety of drug treatments for psoriasis. The study started in 2007 and our aim is to recruit as many participants receiving conventional systemic and biologic treatments until 2028 (current study end date). A biologic is a protein based drug taken from living cells handled in a laboratory. Biologics target specific parts of the immune system that play a role in psoriasis.

Purpose of the study

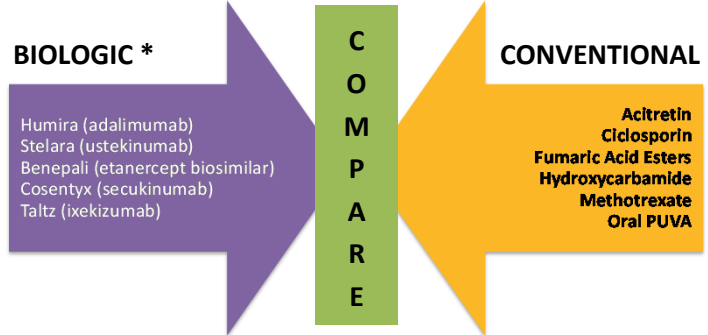


Biologic agents have been tested for safety in clinical trials over a relatively short period of time



BADBIR was established to assess the **long-term safety** of biologics by following a real world population of psoriasis patients from all areas of the United Kingdom and Republic of Ireland

Safety events, or reactions, are *medical occurrences* that may or may not be related to the drug you are receiving. We collect all safety events to investigate whether a drug is related to safety events reported.



* In the past, BADBIR also recruited patients receiving Raptiva (efalizumab), Remicade (infliximab) and up until recently Enbrel (etanercept)

The Process

Most of the dermatology centres in the United Kingdom and Republic of Ireland are taking part in this study and, subject to patient consent, the dermatology team provide data to BADBIR. This is how:

Step 1: Your dermatologist or someone in his/her team will discuss BADBIR with you, if you meet the following criteria for the study:

- Have a diagnosis of psoriasis
- Provide written informed consent
- Currently under the care of a dermatologist and receiving drugs for psoriasis included in BADBIR



Step 2: Via your dermatologist, BADBIR will follow your progress with treatment on a regular basis.

Step 3: Your dermatologist or someone from his/her research team will enter your treatment details and safety events on to the secure BADBIR database.



Step 4: Additionally BADBIR links with other national registries to ensure the greatest capture of safety events experienced as long as the patient is participating in the study. Details of how BADBIR links with national registries can be accessed via the following web link: www.badbir.org.uk

Step 5: The BADBIR research team processes and analyses all data. Rates of safety events are compared between the two study groups (conventional and biologic).

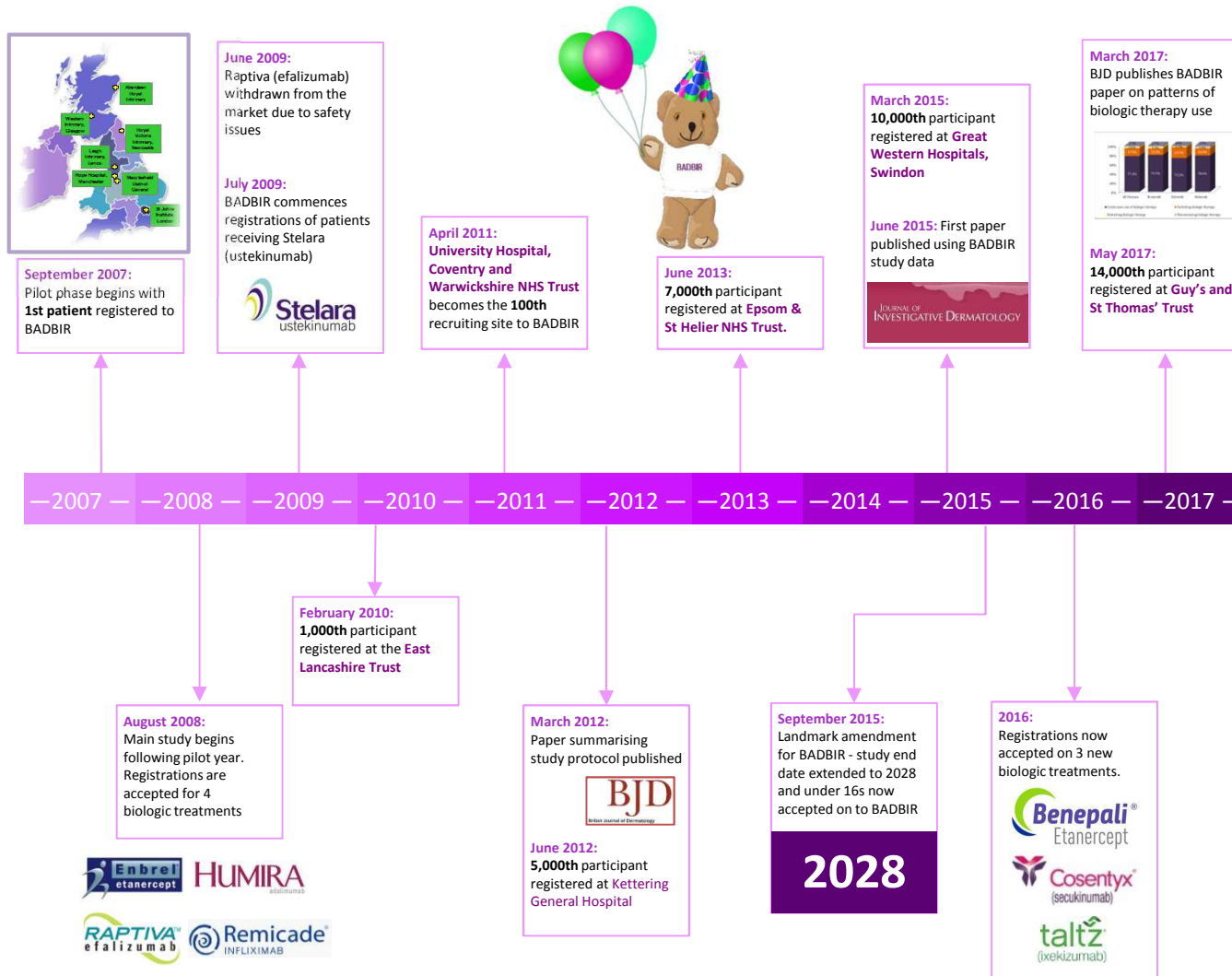


Step 6: The results will ultimately be used to provide healthcare specialists and you (the patient) with a better understanding of any increased risk of the newer therapies.

Celebrating 10 Years

BADBIR has been collecting patient data for 10 years now making it a rich data source.

Since 2007, there have been many milestones achieved. The timeline below illustrates some of these milestones:



Thanks to all BADBIR participants!
 We currently have **14,675** patients on the registry (15/08/2017) and recruit from **156** centres across the United Kingdom and Republic of Ireland



Visit our website www.badbir.org/Participants/ to find out more about BADBIR

We invite staff and patients to follow @BADBIR on twitter

2017 Research Paper Summaries

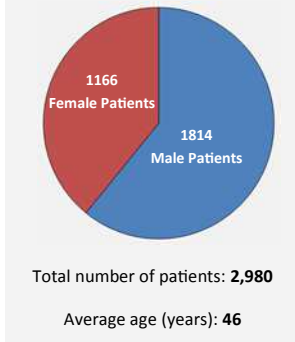
An insight to what your valued participation to BADBIR means in the research world...

1) Patterns of biologic therapy use in the management of psoriasis

Introduction

Drug guidelines provide recommendations on how biologic therapies should be used. However, in some situations doctors may decide to prescribe outside the recommendations. For example, by changing the number of days between the doses or adding in a traditional conventional drug. These changes are often made to get psoriasis under better control.

Who was included in this study?



Research aim

To understand how biologic drugs (Humira, Enbrel and Stelara) were used for the treatment of psoriasis alone and together with conventional treatments such as methotrexate.

What did we find?

During the first **12 months** of starting a biologic treatment:

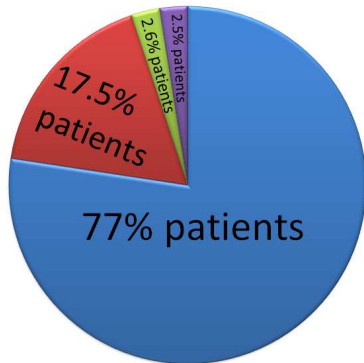
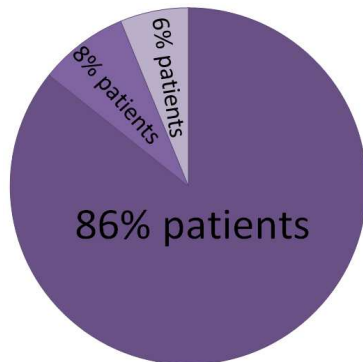


Figure 1. Did Patients Remain on their Biologic Treatment?

- 77% continued on the same biologic
- 17.5% changed to another biologic
- 2.6% had a break and then restarted
- 2.5% stopped biologics with no restart

Figure 2. Did Patients Receive the Recommended Dose?

- 86% received the recommended biologic dose
- 8% received a higher dose
- 6% received a lower dose



Twenty five percent of patients were prescribed a traditional conventional therapy in combination with biologic therapy with methotrexate being the most common.

What does this information mean for patients with psoriasis?

Most patients were treated with the recommended dose. The use of other conventional therapies in combination with biologic therapies should be considered when measuring response to treatment and risk of side-effects.

2) Identification of factors that may influence the selection of biologic therapy for people with psoriasis

Research aim

To investigate whether or not a patient's characteristics influence the first biologic therapy that they are prescribed by dermatologists.

What did we find?

There has been a change in prescribing behaviour over time for Enbrel, Humira and Stelara (see Figure 1 below).

Who was included in this study?

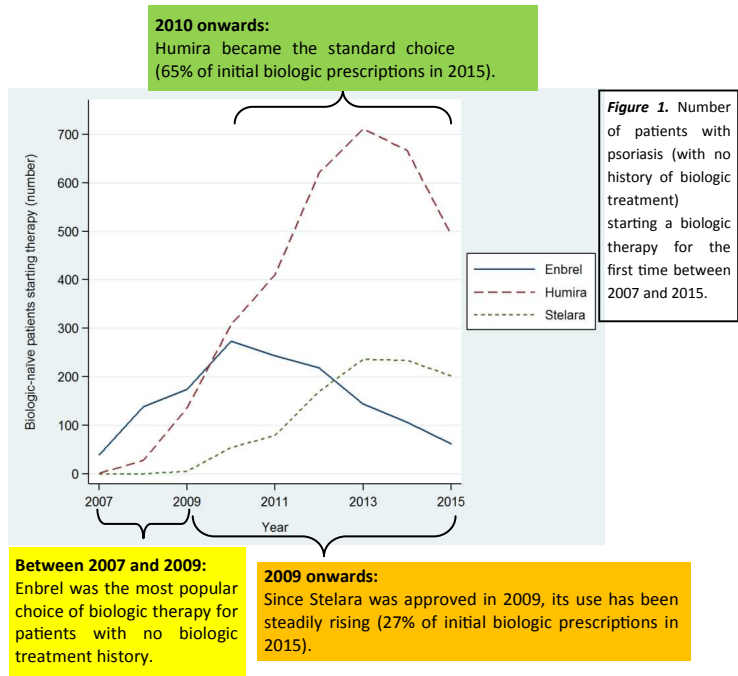
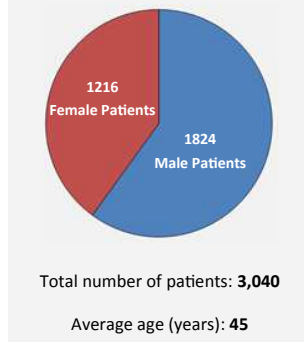


Figure 1. Number of patients with psoriasis (with no history of biologic treatment) starting a biologic therapy for the first time between 2007 and 2015.

The factors that may influence which biologic treatment is given to a first time biologic drug user are:

- Psoriatic arthritis - Patients were more likely to receive **Humira** if they had psoriatic arthritis. This is because Humira can offer a higher chance of improving arthritis for people with psoriasis arthritis compared to Stelara.
- Retired, unemployed, severe psoriasis or weighed over 100kg - Patients were more likely to receive **Stelara**.
- Republic of Ireland resident - Patients were more likely to receive **Enbrel**. This might be because of Enbrel's established long-term safety record, or because of different guidelines for dermatologists in Ireland.

What does this information mean for patients with psoriasis?

There has been a change in the drugs prescribed over time as more drugs are available for use. On an individual level, the results suggest that doctors are considering the patient's other conditions such as presence of psoriatic arthritis when making a decision on the choice of biologic to treat psoriasis. Thanks to patient participation in research such as BADBIR, dermatologists will be able to use the results on the effectiveness and safety of different therapies to help make choices on the drug to use for a particular patient.

2017 Research Paper Summaries

An insight to what your valued participation to BADBIR means in the research world...

3) Comparing how effective biologic therapies are in improving the quality of life in patients with psoriasis

Research aims

- 1) To compare how effective different biologic therapies (Humira, Enbrel and Stelara) are on improving quality of life using Dermatology Life Quality Index (DLQI) and European Quality of Life - five dimensions questionnaire (EQ-5D). A high DLQI score (maximum possible score 30) indicates poor quality of life. In contrast, a high EQ-5D average score indicates good quality of life.
- 2) To identify factors associated with improvements in quality of life

What did we find?

- The use of biologic therapy was linked with big improvements in quality of life over the first 12 months of treatment:

The average DLQI score improved

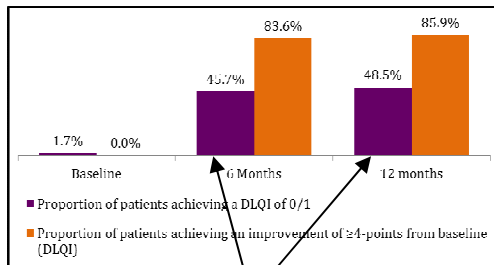


Figure 1. Bar chart showing the proportion of patients scoring 0 or 1 for DLQI vs an improvement of 4 or more points from baseline at baseline and 6 and 12 months.

Nearly 50% of patients reported a total DLQI score of 0 or 1 (indicating no impairment in quality of life) at 6 and 12 months.

The average EQ-5D score improved

Score 1 represents best health

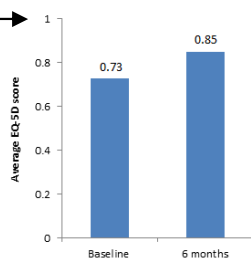


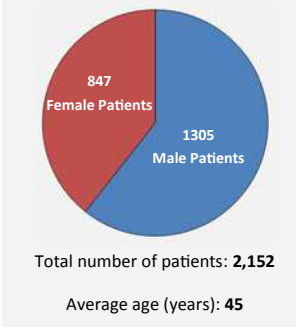
Figure 2. Bar chart showing the average EQ-5D score at baseline and 6 months

The five dimensions of the EQ-5D are:

- Mobility, Self-care, Usual activities, Pain/Discomfort and Anxiety/Depression.

The biggest improvement was in the pain/discomfort area and the smallest improvement was found in the self-care area.

Who was included in this study?



Factors associated with improvements in quality of life

Improvements in quality of life were influenced by the choice of biologic therapy, lifestyle choices and diagnoses of other medical conditions:

- Patients receiving Enbrel were less likely to achieve a total DLQI score of 0 or 1 compared to patients receiving Humira
- Female patients, patients with multiple medical conditions, current smokers as well as obese patients were also less likely to achieve a total DLQI score of 0 or 1 or show improvement in the EQ-5D.

What does this information mean for patients with psoriasis?

We found that biologic therapies improved the quality of life for psoriasis patients and is influenced by (i) the choice of biologic therapy, (ii) lifestyle characteristics (e.g. obesity and smoking) and (iii) other medical conditions. Lifestyle changes, including quitting smoking and weight loss for obese patients, may improve the effectiveness of biologic therapies. The findings should be also considered along with the other known benefits and risks of biologic therapies to help inform selection of the best therapy for patients with psoriasis for improvements in quality of life.

Here is a full list of references of these summaries including the main author and full title of the paper:

References

- 1) Iskandar et al. *Patterns of biologic therapy use in the management of psoriasis: cohort study from the British Association of Dermatologists Biologic Interventions Register (BADBIR)*. BJD 2017;176(5):1297-1307
- 2) Davison et al. *Identification of factors that may influence the selection of first-line biologic therapy for people with psoriasis: a prospective, multi-centre cohort study*. BJD 2017; Epub ahead of print.
- 3) Iskandar et al. *Comparative effectiveness of biologic therapies on improvements in quality of life in patients with psoriasis*. BJD 2017; Epub ahead of print.