

# Welcome

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

BADBIR is an observational research study that was set up by the British Association of Dermatologists (BAD) in 2007 and has been running successfully since. The current study end year is 2028.

The National Institute for Health and Clinical Excellence (NICE) has recommended that all patients in the UK receiving newer therapies for psoriasis should be registered with BADBIR. Once patients have joined BADBIR, they are followed up as normal by their Dermatologist who will provide information to BADBIR via the secure database.

## 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 patients with additional diseases (co-morbidities)

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

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

### Biologic Group

- Amgevita
- Benepali
- Cimzia
- Cosentyx
- Erelzi
- Humira
- Hyrimoz
- Imraldi
- Ilumetri
- Kyntheum
- Raptiva
- Remicade
- Skyrizi
- Stelara
- Taltz
- Tremfya
- Zessly

Patients receiving a biologic therapy

COMPARE

Patients receiving a conventional therapy

Patients receiving a small molecule therapy

### Small Molecule Group

- Skilarence

### Comparison Group

- acitretin
- ciclosporin
- fumaric acid esters
- hydroxycarbamide
- methotrexate
- oral PUVA

# How **YOUR** contribution makes a difference

Almost all dermatology units in UK and Republic of Ireland hospitals are taking part in BADBIR. Once consent has been provided, the dermatology team provide clinical 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 treatments the BADBIR study is researching**

## STEP 2

BADBIR will follow your progress with treatment on a regular basis, via your dermatologist.

Your dermatologist or someone from his/her research team will enter your treatment details and associated medical events onto the secure BADBIR database.

## STEP 3

Additionally, BADBIR links with other national registries to ensure the greatest capture of drug safety events experienced by a patient whilst in the BADBIR study. Details of how BADBIR links with national registries can be accessed via the following link:

[www.badbir.org/Participants/Linkage](http://www.badbir.org/Participants/Linkage)

Summary of the information collected is shown below.

## STEP 4

All data is processed and analysed by the BADBIR research team. The rates of safety events are compared between the three study groups to determine how safe and effective treatments are in treating psoriasis.

## STEP 5

The results will ultimately be used to provide the dermatology community and psoriasis patients with a better understanding of any increased risk on the newer therapies.

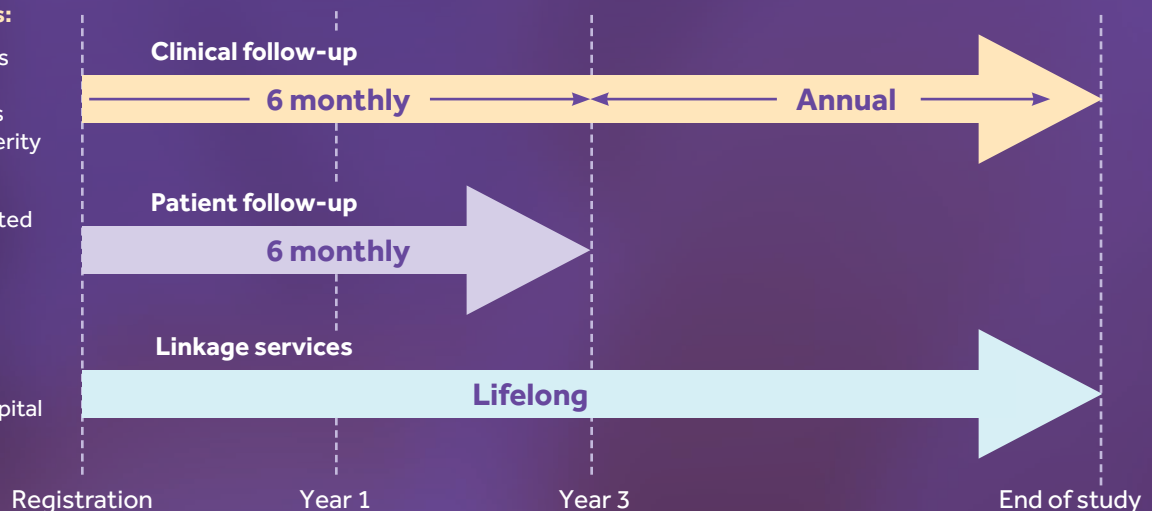
### Summary of the information collected

#### Data collected on Medical histories:

- Comorbidities
- Drug details
- Safety events
- Psoriasis severity

- Patient reported measures
- Lifestyle

- Cancers
- Deaths
- Inpatient hospital admissions



# A big **thank you** to all participants!

We begin 2020 with **164 participating centres** across the United Kingdom and Republic of Ireland and over **19,500 patient registrations!**

BADBIR recruitment in Portsmouth has grown significantly. Dr Shipman (PI) and our dermatology research team are encouraging all eligible patients to join the register. Our patients understand that by joining the register they are contributing to future knowledge of psoriasis and therapeutic safety. Our clinical care team have been key in Portsmouth's success, by making the initial approach to invite patients. This vital step means that we have raised awareness and reached more patients than ever before.

BADBIR has evolved into a huge and highly successful enterprise emblematic of the collaborative nature of British and Irish dermatology. It is now the largest such register in the world and viewed as the "gold standard". Important scientific papers emanating from BADBIR have informed more effective and safer management of people with severe psoriasis. It is a true privilege to be the Chief Investigator of BADBIR; the success is not down to me but to our dedicated BADBIR team in Manchester, the BAD, the staff in all of our recruiting centres and the willingness of patients to consent to participate.

**Professor Chris Griffiths**  
Chief Investigator

I have suffered from severe psoriasis from a young age and experienced the NHS treatment pathway. As both a patient with an autoimmune disease and as a member of various patient communities for people with similar conditions I can understand the frustration of living with a life-long disease. Being a patient representative for BADBIR allows me to contribute towards national conversations around treatments and provide my real-life experience as a patient to groups of engaged clinicians and researchers. As I am in receipt of biologics to manage my condition, I have registered onto the BADBIR study as part of this and understand that it can be easy to forget you are enrolled on the trial. However, it is important to remember how valuable your contribution towards current and future treatments is by signing up and providing your information, and the value this has for clinical research.

**Ellie**  
patient representative



**One of our top 2019 recruiters**  
Portsmouth NHS Trust

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

If you wish to engage with BADBIR feel free to tweet @BADBIR

# COVID-19 and Psoriasis Research

During these unprecedented times with COVID-19 affecting countries across the world, BADBIR is well positioned to research the short term and long term effects of this global pandemic for psoriasis patients along with other research projects such as PsoProtectMe

Coronavirus (COVID-19) is a new infection with many areas of research exploring its impact. There is a particular interest in the impact in psoriasis due to the nature of the illness and the types of drugs used to treat patients. Those receiving an injection or tablet for their psoriasis may have been 'shielded' and asked to minimise contact with others if felt to be 'clinically extremely vulnerable'.

The British Association of Dermatologists and the Psoriasis Association have further information available on their websites:

[www.skinhealthinfo.org.uk](http://www.skinhealthinfo.org.uk)

[www.psoriasis-association.org.uk](http://www.psoriasis-association.org.uk)

## How your contribution to BADBIR will help

By being part of BADBIR you are amongst thousands of people providing their health data to help answer important questions on the safety of psoriasis treatments including biologics. As these drugs act to suppress the immune system, researchers have always been interested in the risk posed by infection.

This is particularly relevant in the coronavirus pandemic. Your contribution will help research whether these treatments increase or decrease the risk of severe COVID-19 infection. BADBIR is able to explore this question using information from psoriasis patients across the UK and Republic of Ireland.

## Clinic Appointments

Since the UK government introduced lockdown measures in March 2020, many clinic appointments have had to be rescheduled or completed remotely over a phone call with dermatologists and research nurses. BADBIR is still able to collect this data through normal channels via our web-based database. However, in order to help our hospital research teams with data collection, we will be launching a brand new area of the BADBIR website in the near future so patients themselves can complete healthcare questionnaires directly.

For updates on any developments keep an eye out on our website: [www.badbir.org](http://www.badbir.org)

## Other research taking place...

PsoProtectMe is a new international registry seeking to answer questions on COVID-19 for psoriasis by surveying patients globally. Other teams are asking people with other important inflammatory conditions, such as eczema and arthritis, similar questions. The teams are working together to share and make the best use of the information.

The PsoProtectMe team are asking everyone around the world with psoriasis, whether or not you have symptoms of COVID-19, to complete the survey:

[www.psoprotectme.org](http://www.psoprotectme.org)

The online survey takes only 5-10 minutes and asks about your symptoms, psoriasis treatments and any underlying health conditions you may have. If you have suffered from COVID-19, we will ask how this has affected you and your psoriasis.

Your information will help further understanding on how the pandemic is affecting people with psoriasis. This will help healthcare professionals make important decisions about the clinical care of people with psoriasis during the pandemic.

BADBIR is a rich data source with over 12 years of data collection. Our researchers ask important questions regarding treatment safety and effectiveness and publish these results for the scientific community. Moreover we want patients and the general public to be informed of BADBIR's findings. We have summarised some of our key findings in this section.

# Hot off the Press

2020 results



## Real-world psoriasis patients vs Clinical trial subjects

We investigated whether patients in BADBIR could have been recruited for clinical trials of Enbrel, Humira or Stelara. We found that patients who would not have been recruited into clinical trials were less likely to achieve the same skin clearance with biologic therapies and were 2- to 3-times more likely to experience a side effect in the first year of therapy.

### Conclusion

This study can help patients and their healthcare professionals to manage their expectations of a therapy as clinical trial results can be misleading.

## How long do patients continue Humira, Stelara and Cosentyx treatments?

We compared the proportion of patients treated with Stelara (88%) and Cosentyx (88%) remaining on therapy at 12 months and found them to be identical. Patients receiving Humira were more likely to stop therapy in the first year (78% remained on therapy), unless they had psoriatic arthritis or were treated received another biologic previously.

### Conclusion

Similar numbers of patients remained on Cosentyx and Stelara at 1 year, while patients receiving Humira did not stay on therapy for as long.

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

We investigated whether patients receiving Stelara, Humira, Enbrel or methotrexate had different risks of developing a new cardiovascular event (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 none of these therapies increases the risk.

BADBIR has published numerous research papers since 2015. These papers mainly focus on drug safety or drug effectiveness. You can find the summaries of these papers in the following pages.

# BADBIR Findings

## Treatment Selection and Predictors



### What are the factors that may influence the selection of biologic therapy for psoriasis?

The following factors were found to affect the choice of biologics (Humira, Enbrel and Stelara) for people with psoriasis:

#### Presence of psoriatic arthritis

Patients with psoriatic arthritis were more likely to receive Humira than Stelara.

#### Patient weight

Patients who weighed over 100 kg were more likely to be given Stelara.

#### Country of registration

Patients in Republic of Ireland were more likely to be treated with Enbrel than UK patients.

#### Employment status

Unemployed or retired patients were more likely to be on Stelara.

#### Disease severity

Stelara was the preferred drug for severe psoriasis.

#### Conclusion

Understanding the factors affecting the choice of biologic therapies to treat psoriasis might enable dermatologists to adopt a more personalised approach when prescribing drugs.

### Which factors can predict biologic therapy effectiveness in psoriasis?

We identified several factors that are associated with poor improvement in disease severity at six months post-treatment:

#### Demographic factor

Female patients had smaller improvements in disease severity compared to males.

#### Social factors

Patients who were unemployed (including due to ill health), ex/current smokers showed little improvement in disease severity.

#### Clinical factors

Patients who were overweight, had small plaque psoriasis, psoriasis of the palms/soles had smaller improvements in disease severity.

#### Conclusion

Some of these factors can be managed which confirms the important role that a dermatologist plays in educating patients about behaviour change and lifestyle management (i.e. quitting smoking and losing weight) in addition to targeted biologic therapy.

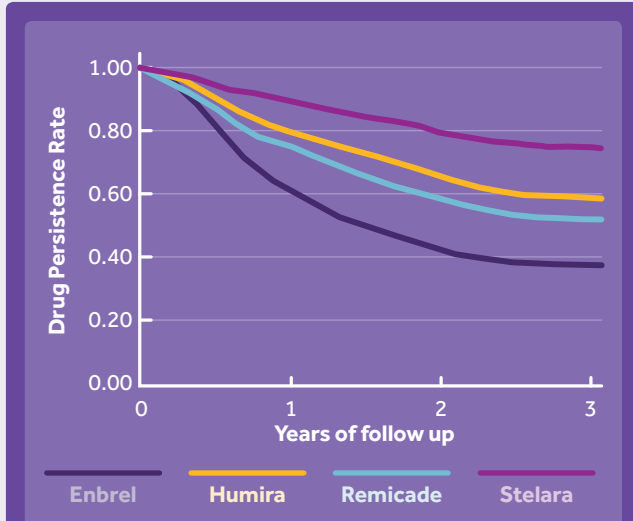
# BADBIR Findings

## Drug effectiveness



### How long do patients stay on biologic therapies for the treatment of psoriasis?

- 77% of patients remained on their biologic after one year, 53% of patients remained after 3 years.
- Current smokers and female patients were more likely to stop biologic therapy.
- Patients who have psoriatic arthritis are less likely to stop their therapy.



Patients receiving Stelara continued psoriasis treatment longer than patients receiving Humira, Remicade and Enbrel respectively.

### Conclusion

This information will form the basis of an informed discussion around biologic therapies i.e. the likelihood that, over time, patients will stop their treatment for a variety of reasons. It will assist patients and their doctors to choose the right biologic therapy for them at the start.

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

- Humira, Enbrel and Stelara improved the patients' quality of life over the first year of treatment, evident from the improved scores from two patient questionnaires: DLQI and EuroQol.
- The biggest improvement was in the pain/discomfort area.

We also explored any factors that were associated with improvements in quality of life. We found that the following factors were less likely to show greater improvements in the quality of life:

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 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.

### Interested to know more?

Please visit our website for further details on BADBIR publications  
[www.badbir.org/publications](http://www.badbir.org/publications)

# BADBIR Findings

## Drug safety information



### Is there a risk of Serious Infection in Patients with Psoriasis Receiving Biologics?

Patients receiving Humira, Enbrel and Stelara did not have a significantly higher risk of serious infections as compared to the control group.

There was 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.

### Is Infliximab associated with an increased risk of serious infection in patients with psoriasis?

Infliximab (Remicade) is associated with increased risk of serious infections when compared with non-biologic therapies in the UK and the Republic of Ireland.

#### Conclusion

This increased risk should be included in drug counselling between the patient and clinician before being prescribed.

### Cumulative Exposure to Biologics and Risk of Cancer in Psoriasis Patients:

Psonet studies from Israel, Italy, Spain, United Kingdom and Republic of Ireland.

Psonet comprises independent drug safety registries that collaborate to investigate the long-term safety and effectiveness of biologic and systemic therapies in patients with moderate-to-severe psoriasis.

In this study, the cumulative length of exposure to biologics was found not to be associated with the risk of developing cancers, even after controlling for the effect of age, gender, location, previous exposure to methotrexate, ciclosporin and phototherapy, duration of psoriasis, and comorbidities. Within registry comparisons gave similar results.

#### Conclusion

Cumulative length of exposure to biologic therapies of psoriasis patients in real-world clinical practice does not appear to be linked to a higher risk of cancer after several years of use.

## Future research questions

Are the conventional treatments effective in treating psoriasis?

What is the risk of different types of cancers?

How effective are newer drugs compared to older more established drugs?

What are the outcomes of pregnancy in women receiving psoriasis treatment?

Can we predict drug safety outcomes by developing specialised programs?

How safe and effective are these therapies in children?

BADBIR has been collecting data on children since 2015. Once we obtain enough data we can investigate safety and drug effectiveness in children also.