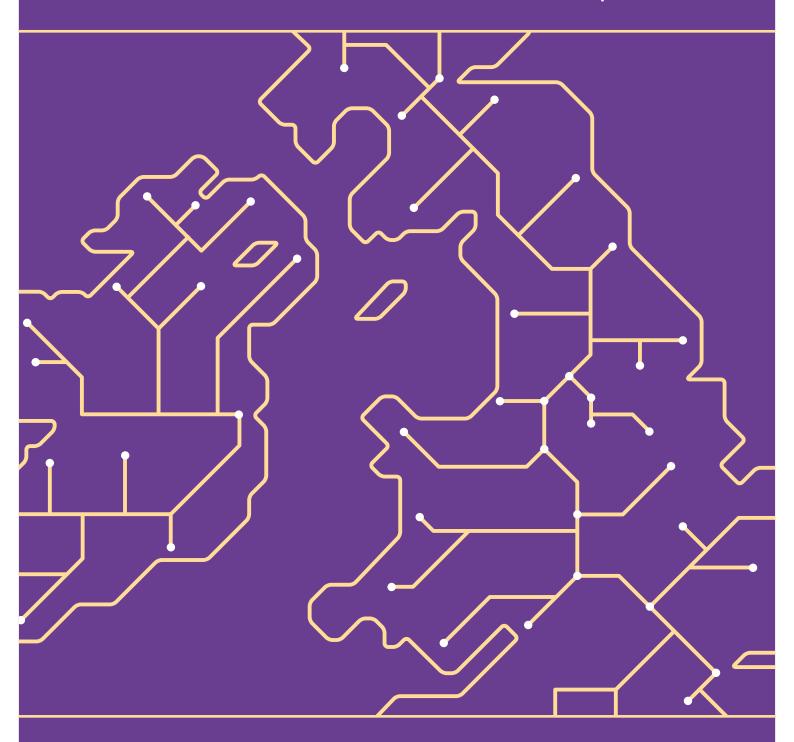




## 2025/26

# BADBIR ANNUAL UPDATE

Monitoring the long-term safety of new treatments for psoriasis



British Association of Dermatologists Biologics & Immunomodulators Register

## Welcome

Welcome to the 2025 update. BADBIR is a world leading pharmacovigilance Register for psoriasis built through the collective effort of the UK and Ireland dermatology community.

The past 12 months on BADBIR have continued to be both productive and rewarding. Our ever-expanding and maturing dataset is enabling researchers to answer important clinical questions, thanks to the ongoing dedication of our participating hospital sites. We are hugely grateful to the Principal Investigators, clinical research teams, and the 20,000 patient-participants whose contributions remain central to BADBIR's ongoing success.

Highlights from the last year include the many excellent journal articles published on themes including safety and comparisons with clinical trial data. Later in this newsletter, we highlight two recent papers on the topic of Drug Survival: one comparing biosimilars with originator adalimumab, and another examining the survival of IL-17 and IL-23 inhibitors. BADBIR has also added almost 1000 new participant registrations to the Register – a significant achievement in our 18th year operating since study start. New hospital sites continue to join. We were delighted to welcome Great Ormond Street Hospital earlier this year and look forward to collaborating on the recruitment of paediatric participants in BADBIR.

As BADBIR approaches the twentyyear milestone, we are actively planning for the future of the Register. Our goal remains clear: to continue delivering robust, high-quality data to support informed decision-making in psoriasis treatment. In the following section, we outline several initiatives currently in development.

#### **New Products**

A strength of BADBIR has been its ability to record exposures on all systemic treatments marketed for psoriasis in the UK. There is now data held on 38 different conventional, biologic originator, biosimilar and small molecule treatments in the Register.

Looking ahead there is great interest in the pipeline of upcoming treatments. We are well placed to monitor new tyrosine kinase 2 (TYK2) and IL-23i oral medications once available in the NHS and will integrate this.

We are also exploring research including relevant concomitant medications used alongside psoriasis treatments in the real-world, including. Glucagon-like peptide-1 (GLP-1) agonists. More information on this will be available soon as plans are finalised.

#### Comparator

As a cohort study, BADBIR's safety analysis has compared outcomes on a group recruited on conventional systemic anti-psoriatic treatments to those starting on biologic and small molecule therapies. We are seeking to now build a new comparator cohort of the established classes of biologics (TNFi and IL-12/23i) to add an alternative and contemporaneous option for safety researchers.

Many BADBIR sites have already recruited new patients across 2024 and 2025 and we welcome new participants to join. Please see the eligibility criteria for details of the treatment registrations are being accepted on.

### **Cross-Registry Projects**

Even with such huge dataset built in the UK and Ireland, BADBIR can benefit from joining up with other equivalent psoriasis Registers to pool data together for a more powerful analysis. Please see the Biosimilars Drug Survival paper summarised on p.11 for a recent example. Here BADBIR teamed up with the Spanish Register BIOBADADERM and the French National Health Data

System (SNDS) to collaboratively address the research question.

We anticipate more of this will follow as rare safety events are looked at in future analyses. It is notable strength of BADBIR that the data structure allows for this type of collaborative work to take place.

## **Data Linkage**

Within BADBIR 's study design usage of data from national providers of healthcare data has been a cornerstone of obtaining comprehensive and high-quality data for analysis. Currently linked patient-level data is received on episodes of inpatient admission, malignancy diagnosis and vital status from organisations including NHS England, Public Health Scotland and the Northern Ireland Cancer Registry.

The benefit of this will be seen on upcoming BADBIR papers on cancer and pregnancy where data from Linkage has bolstered that entered directly by the hospital sites. We are exploring further Linkage on secondary-care prescriptions to add an additional source for how treatment information can be collected.

### **More to Come**

As the Register nears its 20-year milestone, our focus is firmly on the future. With a growing dataset and ongoing high-impact research, we are well-positioned to address emerging clinical questions in the moderate-tosevere psoriasis population. We are dedicated to adding to the existing evidence base as the project continues to evolve. Thank you once again to all those contributing to BADBIR.

**Professor Richard Warren BADBIR Chief Investigator** 

# Eligibility July 2025



## Eliqibility Requirements



Diagnosed with chronic plaque or generalised *pustular* psoriasis



Able to give written informed consent



Patients entering the conventional cohort must be biologic-naive

www.badbir.org/clinicians/eligibility

## **Treatments**

Patients must have started or switched to one of the following psoriasis, within 6 months of the

## **CONVENTIONAL**

- ✓ Methotrexate
- ✓ Acitretin (if patient has GPP)
- ✓ Ciclosporin (if patient has GPP)

#### **BIOLOGICS**

- ✓ Amgevita (adalimumab)
- √ Hulio (adalimumab)
- √ Humira (adalimumab)
- ✓ **Yuflyma** (adalimumab)
- √ Bimzelx (bimekizumab)
- √ Cosentyx (secukinumab)
- ✓ **Ilumetri** (tildrakizumab)
- ✓ **Skyrizi** (risankizumab)
- √ Spevigo (spesolimab)

treatments, for treatment of their date of consent:

## **THERAPIES**

- √ Hyrimoz (adalimumab)
- ✓ **Idacio** (adalimumab)

- √ Stelara (ustekinumab)
- ✓ Tremfya (guselkumab)

### **SMALL MOLECULE**

√ Sotyktu (deucravacitinib)



— III -

**PASI** and **DLQI** 

· Conventional therapy:

PASI ≥10 and DLQI ≥11

(not required if switching

Biologic/small molecule:

diagnosed with GPP)

between conventional drugs or

No minimum scores, but PASI

and DLQI must be recorded

### **Paediatric Patients**

- Under the age of 16 and starting any systemic therapy are eligible
- · No cDLQI score required for conventional treatments



## **Contents**

www.badbir.org email: badbir@manchester.ac.uk

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## **Key** statistics

Through the hard work and commitment of the UK and Ireland dermatology community, BADBIR has grown to be the largest psoriasis study of its kind globally. Here are some key stats to profile the success and scale of the Register.

# 23,026 total registrations



16,209

in Biologic Cohort

170,152

Follow-up Visits recorded on BADBIR

in the Conventional **Comparison Cohort** 

226,546

PASIs collected

in the Small molecule Cohort

**DLQIs** completed

120,520

Adverse events entered



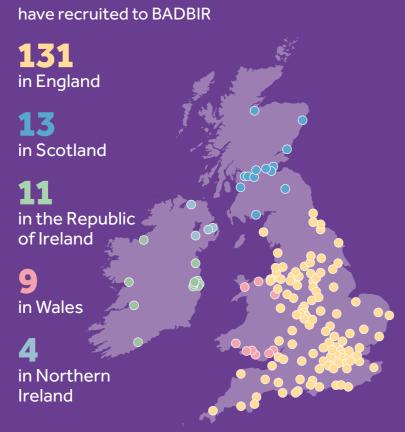
138,000

Person Years Follow-up collected

**Data held on** 

Different Treatments for Psoriasis

## 168 centres



## Evaluating changes in baseline characteristics and drug utilisation pattern in patients with moderate-to-severe psoriasis

The last 20 years have brought major advances in treating moderateto-severe psoriasis, notably with biologics. A recent BADBIR paper in Clinical & Experimental Dermatology aimed to profile changes in the patient population in BADBIR being

treated and receiving systemic therapy and to evaluate changes in utilisation of biologics over time. For more details, this is a link for Alabas et al., 2025 paper published at Clinical and Experimental Dermatology doi: 10.1093/ced/llaf224.

This paper had the most comprehensive demographics data published in BADBIR thus far with over 21,000 registrations included.

## What the baseline characteristics of a BADBIR patient looks like...

They have had psoriasis for

They were vears old on Enrolment

to BADBIR

Arthritis

comorbidity

Most commonly:

Hypertension

**23**%

Depression

were current smokers at study registration

Their Body Mass Index is

years when they were diagnosed with psoriasis

They were

## **Impact**

After 18 years of data collection BADBIR has published 52 papers to date in high quality journals. Many citations have followed in other peer-reviewed journal articles with an ever-growing academic impact evident. Citations are however not the only way to measure the impact of BADBIR's research. A selection of impact metrics generated through the Dimensions and Altmetric tools are summarised here to give indication of how data has been used in the real world. BADBIR was also noted in the NHS Getting it Right First Time review in Dermatology, promoting that departments doing clinical research have better clinical outcomes.

mentions of BADBIR publications in Policy Documents

A standardization approach to compare treatment safety and effectiveness outcomes between clinical trials and real-world populations in psoriasis (2019) in British Journal of Dermatology

Picked up in 7 news outlets following publication Differential Drug Survival of Biologic Therapies for the Treatment of Psoriasis (2015) in the Journal of Investigative **Dermatology** 

Mentioned in 14 Policy Documents internationally

Comparison of Drug Safety Between Clinical Trial Eligible and Ineligible Patients (2018) in JAMA Dermatology

Referenced in

**Technical Appraisals** 

All figure are correct as of 1st June 2025.



## **Get involved** with BADBIR

## **Experience** as Trainee

**Christina Ye** 

After starting dermatology specialist training, BADBIR was one of the first research studies I encountered.

Psoriasis is a common condition frequently seen in general dermatology clinics, and many patients at my local hospital were recruited into the BADBIR registry. This early exposure sparked my interest and led to me apply for the role of Trainee

Representative on the BADBIR Steering Committee.

Over the past two years in this role, I have gained invaluable insights into the complexities of running a longterm observational study. Attending steering committee meetings has deepened my understanding of study logistics, including efforts to support recruitment and reduce missing data. This experience has also highlighted the richness of the BADBIR dataset and the wide range of research questions it can help to address. Additionally, I have come to value the vital role of patient involvement in research, with the patient representative offering

unique insights that help ensure the work remains relevant and meaningful to those living with psoriasis.

My involvement with BADBIR inspired me to develop my own research question, focusing on patients who respond well to systemic treatment. With support from the BADBIR team, I successfully applied for NIHR funding and have now begun a PhD at St John's Institute of Dermatology. My research aims to develop a risk stratification tool to predict the likelihood of maintaining psoriasis control on systemic therapy, with the goal of enabling more personalised long-term management based on individual risk profiles.

## **Experience** as **Clinical Research Fellow**

**Ahmed Hawwa** 

Dr Ahmed Hawwa has recently completed a year in post on BADBIR. As the first postholder of a new Clinical Research Fellow initiative, Ahmed offers some reflections:

I joined the BADBIR Clinical Research Fellowship, having always been curious about the interface between realworld clinical data and evidence-based practice. What I didn't anticipate was the positive impact this fellowship would have on me, not only in developing my analytical skills but in

shaping my future career ambitions in dermatology research.

Early in the fellowship, I attended introductory courses in epidemiology, completed practical tutorials, intensive statistics training including regression and survival analysis, and attended a course on Risk Prediction and Model Development. I soon had access to BADBIR's dataset, a unique resource tracking thousands of patients. Familiarising myself with the structure, data dictionary, and published work from the registry provided a solid foundation for designing my own

The aim of my independent research project was to study neurological adverse events of biologics in patients with moderate-to-severe psoriasis. Hundreds of thousands of drug records were condensed and cleaned, and patient demographics summarised. Comorbidities were identified that could influence primary outcomes of interest such as peripheral neuropathies, CNS demyelination and CNS vascular events. Please look out for an upcoming publication!

For clinicians wondering how research fits into their future, the Fellowship has been a rewarding professional experience for me. My time with BADBIR equipped me with the tools to ask, and sometimes answer. meaningful clinical questions using robust evidence-based datasets. More importantly, it has shown me the value of clinician-led research in improving the care we offer to patients. I encourage any dermatology resident with a passion for research to consider this path.

Interested in using BADBIR data for Research? Please contact **research@bad.org** to enquire about opportunities





## The Psoriasis Association and the Power of Real-World Research

Helen McAteer Chief Executive. **Psoriasis** Association



championed research that puts the patient experience at its heart.

While clinical trials remain vital for testing safety and efficacy under controlled conditions, real-world research—such as that carried out through BADBIR—offers equally crucial insights into how effective treatments are in everyday life.

As a patient support organisation deeply committed to high-quality research, the Psoriasis Association recognises the importance of real-world data in capturing the complexities of living with psoriasis. "Real-world evidence plays a crucial role in bridging the gap between clinical research and the everyday experiences of those managing this condition," explains Helen McAteer, Chief Executive of the Psoriasis Association. "It provides valuable insights into how treatments affect quality of life, adherence, comorbidities, and long-term outcomes—factors that clinical trials often struggle to fully capture."

The Psoriasis Association has supported and promoted involvement in BADBIR since its inception, recognising its role in building a robust picture of biologic therapies in practice. This has informed treatment guidelines, contributed to drug safety profiles, and empowered patients with more transparent information about their options.

Looking ahead, the Psoriasis Association is excited about the evolving landscape of real-world research. Increasingly, digital tools and patient-reported outcome measures (PROMs) are enabling individuals to share their data more directly and regularly. This creates new possibilities for understanding the condition over time and across diverse populations.

Moreover, the Psoriasis Association is keen to see real-world research continue to explore not just the skin symptoms of psoriasis, but its wider impact—including mental health, fatigue, stigma, and the effects of psoriatic arthritis. Psoriasis is more than skin deep, and research should reflect that.

As healthcare continues to move toward personalised and patientcentred care, real-world evidence will be essential in ensuring that treatments are not only effective but truly meaningful to those who

The Psoriasis Association remains committed to promoting and supporting research that actively involves patients and the public, ensuring that the voices, experiences, and needs of those living with psoriasis are heard and represented. Through collaboration with initiatives like BADBIR, the future of psoriasis care will be shaped not just in labs and clinics, but by the lived experiences of patients themselves.

The Psoriasis Association have funded three PhD studentships working on BADBIR with a fourth due to start in 2025.

## **Heber Bright**

"My PhD explores serious infection risks linked to interleukin (IL)-17/ IL-23 inhibitors in psoriasis. I used network meta-analysis to assess clinical trial and real-world data, estimating infection risks across all treatments. Novel findings are under journal review. A completed BADBIR cohort study assessed five-year risks using advanced methods. I'm now investigating recurrent and specific infections. Thesis completion is expected by year-end."

#### **Shamarke Esse**

Shamarke Esse was one of the PhD students in BADBIR who completed his project in 2021. His PhD aimed to determine whether biologic therapy increases cancer risk (excluding keratinocyte skin cancers) compared to conventional systemic therapies. Results showed no elevated cancer risk in psoriasis patients treated with biologics.

#### **Duc Binh Phan**

Duc Binh Phan. a PhD student at the University of

Manchester, studied real-world use of adalimumab biosimilars for psoriasis. Using BADBIR data, he conducted five studies showing biosimilars are effective and safe but switching from Humira leads to higher discontinuation. His work emphasises better patient support and yielded seven publications in leading dermatology journals.



# Profiles spotlight

# Patient representative Perspective

## Olivia Hughes

As a patient with psoriasis, the symptoms of the disease can be difficult to live with.

After previously being prescribed oral immunosuppressant drugs, I have been on biologics for many years. These drugs cleared my psoriasis and had a huge impact on improving my quality of life. In 2022, I joined the BADBIR steering committee as a patient representative, alongside a group of

dermatologists, dermatology nurses, and researchers to improve treatment outcomes, and ensure the work is as patient-centred as possible.

People with psoriasis can use the research findings from BADBIR to make informed decisions about their treatment. For example, I recently had to switch to a different biologic. This was a big decision, and I tried to gather as much information as I could from speaking to my supportive dermatologist and brilliant team of dermatology nurses at Neath Port Talbot Hospital. As well as this, I drew on BADBIR publications to make sure I knew as much as possible about the different options available to me. So far, BADBIR has produced some encouraging results, and as a psoriasis patient being prescribed biologic therapy, I have found it comforting to know this research is being carried out.

Contributing data to BADBIR is now as easy and accessible as possible via the BADBIR Patient Portal.
As a result, dermatology staff no longer need to enter information on patients' behalf, which not only saves time in clinic, but empowers patients to take control of their data.

# GPP and Erythrodermic Value

### Dr Al-Janabi

Relative to other inflammatory skin diseases, plaque psoriasis is well understood at a genetic and immunological level. There are currently 13 unique biologics and several conventional systemics and small molecule agents approved for use in plaque psoriasis. Rarer, severe forms of psoriasis, such as erythrodermic psoriasis (EP) and generalised pustular psoriasis (GPP),

are less well-characterised. While these often co-exist with plaque psoriasis, EP and GPP could represent distinct disease entities with unique risk factors, genetic risk and immunopathogenesis. Gaining a better understanding of these diseases could lead to risk stratification of patients and improved treatment outcomes.

## Why is this Research Important?

Individuals with EP and GPP are often admitted to hospital, and may have a more challenging treatment course relative to those with only plaque psoriasis. To date, there have been few epidemiological studies of EP and GPP, and no genome-wide association

studies. It is important to understand the risk factors and genetic basis of EP and GPP in order to understand their immunopathogenesis and improve treatment outcomes.

## What are we hoping to find?

We hypothesize that EP and GPP carry risk profiles and genetic associations that differ from very severe plaque psoriasis. We hope to find predictive factors indicating which patients with plaque psoriasis might develop EP or GPP, which could contribute to a stratified medicine approach, and pathways or genes predisposing to these phenotypes, which could be targeted therapeutically.

## Using the Patient Portal

## at Belfast Health and Social Care Trust

The team at Belfast Health and Social Care Trust have encouraged the most participants to join the Patient Portal out of all BADBIR centres. We asked them about their experience with the Patient Portal and here is what they told us.

In February 2021, BADBIR approached the Belfast Trust to participate in the Pilot stage for the Patient portal – we took this forward with enthusiasm.

The COVID lockdown necessitated a different way of working. Patients did not attend face-to-face appointments and posting questionnaires was yielding a poor return. Initially recruitment was slow but with feedback from patients and our team working closely with BADBIR staff we were able to identify small changes, which made the process of registration and logging in easier.



Caroline, Halys, Claire, and Dr. McKenna

The majority of feedback received from patients was positive. Some were very keen to use the portal and were delighted as it was easier for them to complete the questionnaires online. It also saved our research team time in clinic and the patients liked that they could complete their questionnaires wherever they were and at their convenience.

There were areas of improvement identified: patients found email reminders were hitting junk or spam folders and some patients found it challenging to remember their username and password. To improve these issues, we have started using iPads in clinic for immediate access to the portal. In addition to this, we developed an easy to remember password management system. We hope this will allow us to see an improvement in overall patient experience, our questionnaire returns, and level of engagement with the Patient Portal.

The best advice regarding engaging patients with the Portal is to be enthusiastic about the benefits of using the Portal and to make the process as easy as possible for the patient.

## Exciting developments: our new database and website

After years of working with our original database, we are pleased to announce the development of a new, more efficient platform designed to better support clinicians and research teams.

This upgrade represents a major step forward in our ability to manage and utilise clinical data more effectively.

Led by Ollie and Hassan, who have dedicated countless hours to this initiative, the project has focused on streamlining functionality and improving usability. The new database is currently in the testing phase. Once initial bugs have been resolved, a second round of testing will take place to ensure robustness and reliability.

We're developing a more modern web system to replace the current ageing one, which will have a more consistent layout, improvements to managing patients and entering follow-ups, as well as being more reliable and maintainable by us. We look forward to sharing this with you later this year, and we welcome your feedback to ensure we keep making it easier for your centre to recruit and follow-up patients to the BADBIR study!

Ollie Steer, BADBIR Research Software Engineer

Looking ahead, training resources will be developed to support a smooth transition. The database team will be producing a series of training videos using Adobe Captivate, designed specifically for database users. These resources will serve as an accessible guide for navigating the new system.

In parallel, we are also in the process of launching a brand-new website. Set

to go live around the same time as the database, the new website will provide a refreshed digital presence, offering clearer access to resources and better support for our global network of users.

Together, these projects represent a significant milestone in our ongoing efforts to modernise systems and improve the tools available to our community.



## **Key Publications**



https://doi.org/10.1111/jdv.20739

Drug survival of IL-23 and IL-17 inhibitors versus other biologics for psoriasis: A British Association of Dermatologists Biologics and Immunomodulators Register cohort study

Dr Leila Motedayen Aval *et al.* JEADV, 2025



#### Questions

What is the real-world drugsurvival of newer IL-23p19 (guselkumab, risankizumab) and IL-17 (secukinumab, ixekizumab, brodalumab) inhibitors compared with established biologics adalimumab and ustekinumab?

#### **Findings**

In 19,034 psoriasis treatment courses from BADBIR (median follow-up = 2.3 years),guselkumab and risankizumab the two IL-23p19 inhibitors showed the longest two-year adjusted drug-survival times for both effectiveness (restricted mean survival time = 1.93 years each) and safety (1.92 and 1.94 years, respectively), outperforming every other biologic except ustekinumab for safety. Ustekinumab's safety survival (1.92 years) equalled the IL-23p19 drugs, but its effectiveness survival was lower (1.84 years) and dropped further in patients with psoriatic arthritis (PsA), where it fell to parity or below the IL-17A inhibitors. Among the IL-17 agents, secukinumab (1.80/1.89 years for effectiveness/safety) and ixekizumab (1.87/1.86 years) maintained moderate persistence, while brodalumab (IL-17R blockade) recorded the shortest effectiveness survival at 1.75 years yet retained safety similar to the other IL-17 drugs and adalimumab. On average, patients remained on IL-23p19

inhibitors about 21 weeks longer for effectiveness and 13 weeks longer for safety than on comparators. Treatment line and comorbidity modified these patterns: prior biologic failure produced the steepest survival decline for IL-17 inhibitors, whereas psoriatic arthritis selectively shortened ustekinumab persistence but left IL-23p19 drugs largely unaffected.

#### Meaning

Our study provides a largescale real-world comparison of risankizumab and guselkumab, confirming their highly similar drug survival profiles, an important insight for clinicians considering IL-23p19 inhibitors as longterm treatment options. Both agents offer good persistence for effectiveness and safety, particularly valuable for patients with previous biologic failures. Additionally, we present novel findings on brodalumab, demonstrating drug survival comparable to adalimumab and IL-17A inhibitors. Contrary to expectations, IL-17 receptor blockade with brodalumab did not prevent the reduction in treatment persistence observed after prior biologic exposure, highlighting a consistent vulnerability across all IL-17 inhibitors. These findings emphasise the role of prior biologic use and comorbid PsA as key considerations influencing biologic selection in clinical practice and empower shared decision-making and personalised sequencing of biologics in psoriasis care.

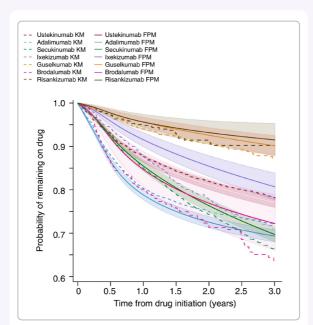


Figure 1

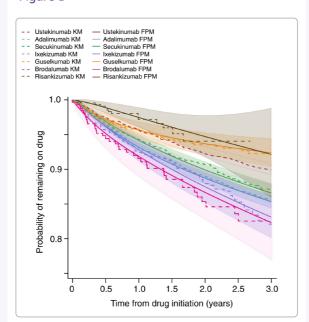


Figure 2

Kaplan-Meier plots reproduced from publication. For full analysis please refer to article.





https://doi.org/10.1093/bjd/ljae454

## Drug Survival and Safety of Biosimilars Compared with Originator Adalimumab for Psoriasis: A Multinational Cohort Study

Duc Binh Phan<sup>1</sup>, MSc; Hugo Jourdain<sup>2</sup>, PhD; Miguel Angel Descalzo-Gallego<sup>3</sup>, PhD; Alicia González-Quesada<sup>4</sup>, PhD; Mahmoud Zureik<sup>2</sup>, PhD; Raquel Rivera-Díaz<sup>5</sup>, PhD; Antonio Sahuquillo-Torralba<sup>6</sup>, PhD; Mark Lunt<sup>7</sup>, PhD; Ignacio Garcia-Doval<sup>3,8</sup>, PhD; Emilie Sbidian<sup>2,9</sup>, PhD; Richard B Warren<sup>1</sup>, PhD; Zenas Z N Yiu<sup>1</sup>, PhD.

#### Questions

How do adalimumab biosimilars compare to the originator drug Humira in terms of drug survival and safety for the treatment of psoriasis in realworld clinical settings? What are the outcomes for patients who switch from Humira to biosimilars?

#### **Findings**

This multinational cohort study evaluated real-world evidence using data from three large national registries: the French National Health Data System (SNDS), the British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR), and the Spanish Registry of Systemic Therapy in Psoriasis (BIOBADADERM). The study included two sets of comparative cohorts: those with no history of adalimumab treatment (adalimumab naïve), starting adalimumab biosimilars were compared with those starting Humira (new users); and those switching from Humira to a biosimilar (switchers) were compared with those continuing Humira treatment. Patients were matched 1:1 based on prior exposure to adalimumab to ensure comparability between groups.

adalimumab biosimilars were matched with 7,387 new users of Humira, while 3,654 patients who switched from Humira to a biosimilar were matched with 3,654 patients who continued on Humira. Among new users, treatment discontinuation rates were comparable between biosimilars and Humira (hazard ratio [HR]: 0.99; 95% confidence interval [CI]: 0.94-1.04), and no significant differences were observed in the incidence of serious adverse events (SAEs) (incidence rate ratio [IRR]: 0.91; 95% CI: 0.80-1.05). However, patients who switched from Humira to a biosimilar had a significantly higher risk of discontinuing treatment than those who remained on Humira (HR: 1.35: 95% CI: 1.19-1.52). Notably, 35% of switchers who discontinued their biosimilar switched

back to Humira. Despite the increased discontinuation risk among switchers, the incidence of SAEs remained comparable between switchers and patients who continued on Humira (IRR: 0.92; 95% CI: 0.83–1.01).

### Meaning

Adalimumab biosimilars demonstrated comparable drug survival and safety to Humira in adalimumab-naïve patients with psoriasis, supporting their use as a cost-effective alternative in routine clinical care. However, patients who switch from Humira to a biosimilar may face a higher likelihood of discontinuation. These findings highlight the importance of providing adequate information, reassurance, and clinical support during switching to ensure treatment continuity and optimise patient outcomes.

		Biosimilar new users vs Humira new users	Biosimilar switchers vs Humira continuous users
All-cause discontinuation (Fully adjusted HR, 95% CI)	BADBIR	0.98 (0.85 - 1.13)	1.35 (1.19 - 1.53)
	BIOBADADERM	0.98 (0.80 - 1.20)	NA
	SNDS	0.99 (0.94 - 1.04)	1.28 (1.18 - 1.40)
	Total	0.99 (0.94 - 1.04)	1.35 (1.19 - 1.52)
	Heterogeneity I <sup>2</sup>	0%	0%
Serious adverse	BADBIR	0.80 (0.66 - 0.97)	0.89 (0.74 – 1.07)
events (IRR, 95% CI)	BIOBADADERM	0.34 (0.20 - 0.58)	NA
,	SNDS	1.05 (0.98 – 1.11)	0.93 (0.83 – 1.04)
	Total	0.91 (0.80 - 1.05)	0.92 (0.83 - 1.01)
	Heterogeneity I <sup>2</sup>	90.9%	0%

Table 1. Meta-analyses of study outcomes stratified by each database

**Abbreviations:** HR, hazard ratio; IRR, incidence rate ratio; Cl, confidence interval; SNDS, French National Health Data System; BADBIR, British Association of Dermatologists Biologics and Immunomodulators Register; BIOBADADERM, Spanish Registry of Systemic Therapy in Psoriasis; NA, not available.

#### uthors

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- 6. Department of Dermatology, Hospital Universitario y Politecnico La Fe, Valencia Spain
- Versus Arthritis Epidemiology Unit, The University of Manchester, Manchester, United Kingdom.
- 8. Department of Dermatology, Complexo Hospitalario Universitario de Vigo, Vigo, Spain
- EpiDermE Epidemiology in Dermatology and Evaluation of Therapeutics, Paris Est Créteil University, Henri Mondor Hospital, Assistance Publique-Hôpitaux de Paris (AP-HP), Créteil, France.





## **BADBIR Publication Directory**

The British Association of Dermatologists Biologic Interventions Register (BADBIR): Design, Methodology and Objectives, Burden et al., BJD, 2012.

Biological therapies for the treatment of severe psoriasis in patients with previous exposure to biological therapy: a costeffectiveness analysis, Sawyer *et al.*, PharmacoEconomics, 2014.

Differential Drug Survival of Biologic Therapies for the Treatment of Psoriasis: A Prospective Observational Cohort Study from BADBIR, Warren *et al.*, JID, 2015.

Demographics and disease characteristics of patients with psoriasis enrolled in BADBIR, Iskandar *et al.*, BJD, 2015.

Generating EQ-5D-3L Utility Scores from the Dermatology Life Quality Index: A Mapping Study in Patients with Psoriasis, Davison *et al.*, Value in Health, 2017.

Intentional and Unintentional Medication Non-Adherence in Psoriasis: The Role of Patients' Medication Beliefs and Habit Strength, Thorneloe *et al.*, JID, 2017. Patterns of biologic therapy use in the

Patterns of biologic therapy use in the management of psoriasis: cohort study from BADBIR, Iskandar *et al.*, 2017, BJD.

Comparative effectiveness of biologic therapies on improvements in quality of life in patients with psoriasis, Iskandar *et al.*, BJD, 2017.

Identification of Factors That May Influence the Selection of First-Line Biological Therapy for People With Psoriasis: A Prospective, Multicentre Cohort Study, Davison et al., BJD, 2017.

Differential drug survival of second-line biologic therapies in psoriasis patients: observational cohort study from BADBIR, Iskandar *et al.*, JID, 2018.

Risk of Serious Infection in Patients With Psoriasis Receiving Biologic Therapies: A Prospective Cohort Study From BADBIR, Yiu et al., JID, 2018.

Comparison of Drug Discontinuation, Effectiveness, and Safety Between Clinical Trial Eligible and Ineligible Patients in BADBIR, Mason *et al.*, JAMA Derm, 2018.

Cumulative exposure to biologics and risk of cancer in psoriasis patients: a meta-analysis of Psonet studies from Israel, Italy, Spain, UK and Republic of Ireland, Garcia-Doval *et al.*, BJD, 2018.

HLA-C\*06:02 genotype is a predictive biomarker of biologic treatment response in psoriasis, Dand *et al.*, Journal of Allergy and Clinical Immunology, 2018.

Identifying demographic, social and clinical predictors of biologic therapy effectiveness in psoriasis: a multicentre longitudinal cohort study, Warren *et al.*, BJD, 2018.

Infliximab Is Associated With an Increased Risk of Serious Infection in Patients With Psoriasis in the U.K. And Republic of Ireland: Results From BADBIR, Yiu *et al.*, BJD, 2019. Development and Validation of a Multivariable Risk Prediction Model for Serious Infection in Patients With Psoriasis Receiving Systemic Therapy, Yiu *et al.*, BJD, 2019.

Persistence and effectiveness of non-biologic systemic therapies for moderate-to-severe psoriasis in adults: a systematic review, Mason *et al.*, BJD, 2019.

Association of Serum Ustekinumab Levels With Clinical Response in Psoriasis, Tsakok *et al.*, JAMA Derm, 2019.

A Standardization Approach to Compare Treatment Safety and Effectiveness Outcomes Between Clinical Trials and Real-World Populations in Psoriasis, Yiu *et al.*, BJD, 2019.

Using Real-World Data to Guide Ustekinumab Dosing Strategies for Psoriasis: A Prospective Pharmacokinetic-Pharmacodynamic Study, Pan et al., Clinical & Translational Science, 2020

Risk of Major Cardiovascular Events in Patients With Psoriasis Receiving Biologic Therapies: A Prospective Cohort Study, Rungapiromnan *et al.*, JEADV, 2020.

Psoriasis treat to target: defining outcomes in psoriasis using data from a real-world, population-based cohort study, Mahil *et al.*, BJD, 2020.

BADBIR: a centenary celebration of research collaboration in British dermatology, Yiu *et al.*, BJD, 2020.

Drug survival of adalimumab, ustekinumab and secukinumab in patients with psoriasis: a prospective cohort study from BADBIR, Yiu *et al.*. BJD. 2020.

Randomized Trial Replication Using Observational Data for Comparative Effectiveness of Secukinumab and Ustekinumab in Psoriasis: A Study From BADBIR, Yiu et al., JAMA Derm, 2020.

Characteristics and skin cancer risk of psoriasis patients with a history of skin cancer in BADBIR, Mason *et al.*, JEADV, 2021.

Defining Trajectories of Response in Psoriasis Patients Treated with Biologic Therapies, Geifman *et al.*, BJD, 2021

Risks of basal cell and squamous cell carcinoma in psoriasis patients after treatment with biologic vs non-biologic systemic therapies, Mason *et al.*, JEADV, 2021.

Differences in Clinical Features and Comorbid Burden between HLA-C\*06:02 Carrier Groups in >9,000 People with Psoriasis, Douroudis *et al.*, JEADV, 2021.

Application of information theoretic feature selection and machine learning methods for the development of genetic risk prediction models, Jalali-Najafabadi *et al.*, Scientific Reports, 2021.

Drug Survival Associated With Effectiveness and Safety of Treatment With Guselkumab, Ixekizumab, Secukinumab, Ustekinumab, and Adalimumab in Patients With Psoriasis, Yiu et al., JAMA Derm, 2022.

Associations between psoriatic arthritis and mental health among patients with psoriasis: A replication and extension study using BADBIR, Lada *et al.*, SHD 2022.

Effectiveness and persistence of acitretin, ciclosporin, fumaric acid esters and methotrexate for patients with moderate-to-severe psoriasis, Alabas *et al.*, BJD, 2023. Uptake of tumour necrosis factor - alpha

inhibitor biosimilars for psoriasis: A drug utilisation study from BADBIR, Phan *et al.*, 2023, BJD.

Atopic Polygenic Risk Score Is Associated with Paradoxical Eczema Developing in Patients with Psoriasis Treated with Biologics, AlJanabi *et al.*, JID, 2023.

Effectiveness and survival of methotrexate versus adalimumab in patients with moderate-to-severe psoriasis, Alabas *et al.*, BJD, 2023.

Characteristics of 'super responders' and 'super nonresponders' to first biologic monotherapy for psoriasis: a nested casecontrol study ,Mason *et al.*, BJD, 2023.

The association of age at psoriasis onset and HLA-C\*06:02 with biologic survival in patients with moderate-to-severe psoriasis: a cohort study from the British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR), Alabas et al., BJD, 2024.

Uptake of tumour necrosis factor-alpha inhibitor biosimilars for psoriasis: a drug utilization study from the British Association of Dermatologists Biologic and Immunomodulators Register (BADBIR), Phan et al., BJD, 2023.

Biosimilars for the Treatment of Psoriasis: A Systematic Review of Clinical Trials and Observational Studies, Phan *et al..*, JAMA Derm, 2023.

Risk of Paradoxical Eczema in Patients Receiving Biologics for Psoriasis, Al-Janabi *et al.*, JAMA Derm, 2024.

Risk of Suicide and Suicidality in Patients with Moderate to Severe Psoriasis, G. Lada *et al.*, CED, 2024.

Drug Survival and Safety of Biosimilars Compared with Originator Adalimumab for Psoriasis, Phan *et al.*, BJD, 2024.

The association of age with biologic survival in patients with moderate-to-severe psoriasis: a cohort study from BADBIR, Alabas *et al.*, B.ID. 2025.

Evaluating changes in baseline characteristics and drug utilisation pattern in patients with moderate-to-severe psoriasis: findings from BADBIR, Alabas *et al.*, CED, 2025.

Drug survival of IL-23 and IL-17 inhibitors versus other biologics for psoriasis, Motedayen Aval, Yiu *et al.*, JEADV, 2025.

Trial emulation of OPTIMAP - does concomitant use of methotrexate affect the survival and effectiveness of adalimumab?, Yiu et al., JAMA Derm, 2025.