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BIR
Biologics and Immunomodulators Register

2026/27

BADBIR ANNUAL UPDATE

Monitoring the long-term safety of new treatments for psoriasis

British Association of Dermatologists Biologics & Immunomodulators Register

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

Welcome

Welcome to the 2026 update. BADBIR is a world-leading real-world data resource for psoriasis, built through the collective effort of the UK and Ireland dermatology community.

Over the past year, BADBIR has continued to make strong and meaningful progress. 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 more than 20,000 patient participants whose contributions remain central to BADBIR's ongoing success.

Highlights from the last year include a strong portfolio of high-quality publications spanning safety outcomes and real-world treatment effectiveness. In particular, we are pleased to feature on p.12 the recent paper led by Dr Binh Phan, published in the British Journal of Dermatology, examining first-line systemic treatments. 7 This work represents an important contribution to understanding treatment pathways and outcomes in routine clinical practice, reinforcing BADBIR's role in generating impactful real-world evidence.

BADBIR added close to 1,000 new participant registrations to the register—an important achievement as we continue into the 19th year since project inception. 2027 is the 20th anniversary of the first participants recruited in BADBIR and we look forward to announcing plans to mark this significant occasion in due course.

Developing Capability and Insight

We are pleased to see continued growth in BADBIR's research capability. This includes the support of a PhD student focusing on healthcare economics, helping to expand the register's contribution to understanding the wider value and impact of psoriasis treatments within the healthcare system.

We are also pleased to highlight the recent completion of work by our Clinical Research Fellow Dr Ahmed Hawwa on neurological events within the BADBIR dataset. Please look out for the full publication soon. We remain committed to supporting emerging researchers through Clinical Research Fellow opportunities using BADBIR's data and are pleased to be offering this pathway again with a new Fellow due to take up post later this year.

Collecting Data on All Systemic Treatments

A strength of BADBIR has been its ability to capture exposures across all systemic treatments marketed for psoriasis in the UK. There is now data held on 39 different conventional, biologic originator, biosimilar, and small molecule treatments within the register.

The last year we have seen a significant influx of data on ustekinumab biosimilar products Pyzchiva, Steqeyma, Uzpruvo and Wezenla. We encourage all sites to continue recording switches from originator to biosimilar to help profile

Looking ahead, we are well positioned to monitor new tyrosine kinase 2 (TYK2) and IL-23 inhibitor oral medications once available within the NHS and will incorporate these into the dataset.

We are also exploring research into relevant concomitant medications used alongside psoriasis treatments in real-world settings, including glucagon-like peptide-1 (GLP-1) agonists. Further information will be shared as these plans are developed.

Use of Systemics in Paediatrics

On page 5 my colleague Professor Tess McPherson summarises progress with recruiting children and younger people into BADBIR. Providing high quality longitudinal to support improved understanding and management of this important patient group remains a key objective of the Register. We are seeking to improve our recruitment of paediatrics and encourage anyone prescribing systemics to get in touch to help us build best dataset possible to address important future questions.

Collaborative Research: MERMAID Project

Collaboration remains a key strength of BADBIR following success alongside BSTOP and PSORT. A notable current initiative is the MERMAID project, led by Dr Zenas Yiu. MERMAID (*Mastering Effectiveness Research by Meta-Analysing Trial and Real-World Evidence in Immune-Mediated Inflammatory Diseases*) is a five-year MRC–funded research programme. The study aims to develop new methods for combining evidence from randomised clinical trials with real-world data collected through national disease registries. Data is provided from BADBIR alongside that from other immune-mediated inflammatory disease registers in the UK on inflammatory bowel disease, rheumatoid arthritis and lupus.

MERMAID will develop innovative methods that allow foundational BADBIR data on the safety, effectiveness and persistence of biologic therapies in routine practice to be analysed alongside clinical trial evidence. This will strengthen confidence in real-world findings and help to ensure that evidence generated through BADBIR can better inform treatment guidelines, policy decisions and personalised care for people living with psoriasis.

More to Come

As the register approaches its 20-year milestone, our focus remains firmly on the future. With a growing dataset, expanding research capability, and ongoing high-impact collaborations, BADBIR is well positioned to address emerging clinical questions in the moderate-to-severe psoriasis population.

We remain committed to delivering robust, high-quality data to support informed decision-making in psoriasis treatment. Thank you once again to all those contributing to BADBIR.

Professor Richard Warren
BADBIR Chief Investigator

Eligibility

July 2026

BIR Biologics and Immunomodulators Register

Eligibility Requirements

- Must have a diagnosis of chronic plaque or generalised pustular psoriasis
- Must provide written informed consent
- Therapy must be ongoing at the time of consent
- Must have started or switched therapy within six months of the date of consent
- PASI and DLQI must be recorded within six months prior to therapy starting
- Patients should be added to the BADBIR database within six months of consenting

Treatments

Patients must have started or switched to one of the following treatments, for their psoriasis, within 6 months of the date of consent:

CONVENTIONAL THERAPIES

✓ **Methotrexate**

BIOLOGICS

✓ **Amgevita** (adalimumab)
✓ **Bimzelx** (bimekizumab)
✓ **Cosentyx** (secukinumab)
✓ **Hulio** (adalimumab)
✓ **Humira** (adalimumab)
✓ **Hyrimoz** (adalimumab)
✓ **Idacio** (adalimumab)
✓ **Ilumetri** (tildrakizumab)
✓ **Skyrizi** (risankizumab)
✓ **Spevigo** (spesolimab)
✓ **Stelara** (ustekinumab)
✓ **Tremfya** (guselkumab)
✓ **Yuflyma** (adalimumab)

SMALL MOLECULE

✓ **Not currently recruiting**

PASI and DLQI

- **Conventional therapy:** PASI ≥ 10 and DLQI ≥ 11 *(not required if switching between conventional therapies or diagnosed with GPP)*
- **Biologic/small molecule:** No minimum DLQI and PASI scores, but scores must be entered

Paediatric Patients

- Under the age of 16 and starting **any** systemic treatment
- No cDLQI score required for conventional treatments

www.badbir.org/clinicians/eligibility

Contents

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

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.

23,545 total registrations

16,680
in Biologic Cohort

6,432
in the Conventional Comparison Cohort

433
in the Small molecule Cohort

183,324
Follow-up Visits recorded on BADBIR

240,093
PASIs collected

119,902
DLQIs completed

130,990
Adverse events entered

153,149
Person Years Follow-up collected

58
Journal Articles Published Using Data from BADBIR

Data held on 39
Different Systemic Treatments for Psoriasis

168 centres
have recruited to BADBIR

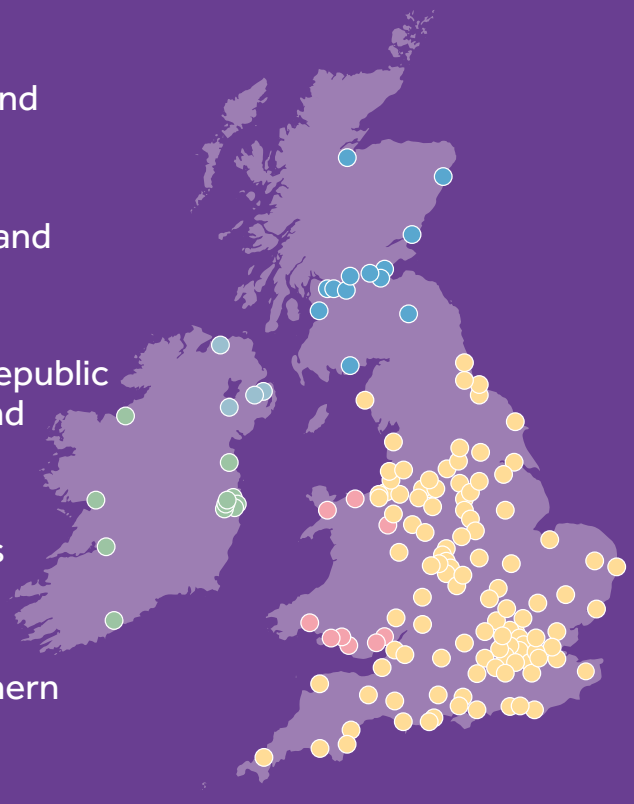
131
in England

13
in Scotland

11
in the Republic of Ireland

9
in Wales

4
in Northern Ireland



All figure are correct as of 1st June 2025.

The Importance of **Paediatric recruitment in BADBIR**

Dr Tess McPherson and Dr Sabrina Khan
Oxford University Hospitals NHS Foundation Trust

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. Psoriasis can have a huge impact on many aspects of life in these age groups and is known to have a long-term life impact.

Reminder: ANY systemic or biologic is eligible for paediatric registration and DLQI score does NOT need to be >10

A paediatric participant is a patient **younger than 16 years old** at the time of consent. However, the required consent forms vary depending on age at time of consent:

- Participant under 11 years of age at time of consent
  Parent or Guardian Consent Form required
- Participant 11 to 15 years of age at time of consent
  Parent or Guardian Consent Form AND Patient Assent Form required
- Participant 16 years of age or older at time of consent
  Patient Consent Form required

Please contact the BADBIR team via **badbir@manchester.ac.uk** or **0161 306 1896** if you have any questions or issues with recruitment of paediatric patients – the team are keen to support you!

BADBIR has included recruitment of children (under 16) since 2015. The inclusion of children and young people in this database, which enables monitoring of use of medication, efficacy, short and longer-term safety, is vital.

Children are NOT little adults and there are many important differences across age including lifestyle, co-morbidities (and potential future co-morbidities), immunology, infection exposure and psychological impact. These factors are crucial when considering, for example, the impact of immunosuppressive therapy on an immature immune system and ongoing effects of cytokine blockade in children as they develop into adults. Additionally, lifetime exposure times are inevitably longer in younger patients (due to the chronic nature of the disease), possibly resulting in a different safety profile than that seen in adults and a potentially higher risk of malignancy and infection.

Data has previously shown variable management of paediatric patients (Lam et al, 2015) and poor monitoring of medications in this age group (Bronckers et al, 2017). Over the past decades treatment options have rapidly expanded and there is a need for better guidance on what to use, when and how. Many treatments are unlicensed in children but are nonetheless important options and often used as first line medications, such as methotrexate. New(er) medications including biologics have been licensed in children since 2009, based on trials which show excellent efficacy and short-term safety. However, they remain expensive and without long term data, particularly in younger age groups. A real need persists for real world data, longer term follow-up and robust health economics for all medications.

Evidence suggests that whereas previously children and young people may have been relatively undermanaged, there is a move to more effective control of psoriasis (Menter et al, 2020). As use becomes more frequent, the need for pharmacovigilance for systemic medications in this cohort becomes even more urgent. BADBIR is a fantastic initiative providing real world data and few other countries have such good prospective data sets including children, thus allowing their seamless follow-up as they move into adulthood.

We have commenced work to examine paediatric patients registered on the BADBIR database (Khan et al, 2021). Ongoing work will include analyses of other patient characteristics such as patient reported outcomes, body mass index, co-morbidities, efficacy any adverse effects of systemic therapy. We are also collaborating with colleagues managing paediatric psoriasis patients (including European colleagues and PsoNET) to combine data sets.

BADBIR has achieved so much over the almost 20 years of existence and continues to highlight the need for real world data. Paediatric recruitment has however, remained low and we believe under representative. We are sure that there are many eligible paediatric patients in the UK who have not been registered with BADBIR and this is a current strategic focus.

Please include paediatric patients in BADBIR when eligible and encourage colleagues to do so too. This is vital for our understanding of the risks and benefits of treatment in younger patients.

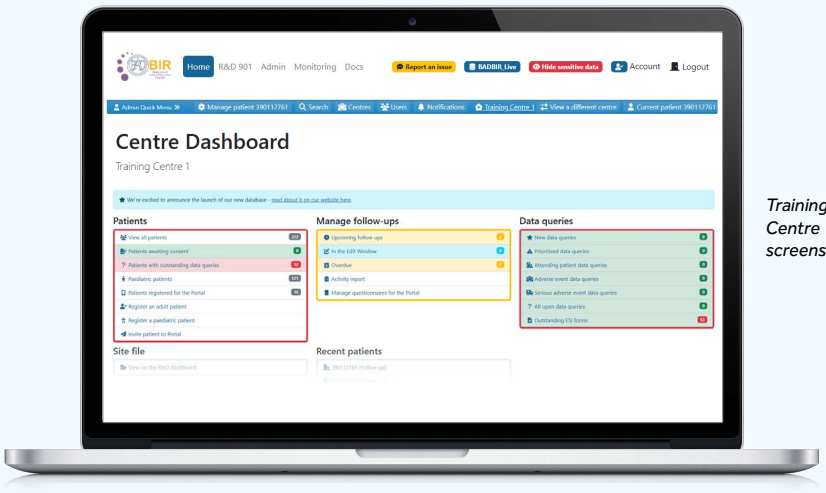
The new BADBIR Web System **for Clinicians**

The new BADBIR Web System for Clinicians, released in February 2026, marks a planned transition from our legacy platform to a modern, secure, risk-aware and scalable system.

This project represents a major milestone for the Register, led by the BADBIR Software Development Team and supported by colleagues across BADBIR, with the aim of supporting the growing technological, operational and research demands of the Register. While many of the core strengths of the previous system have been retained, the new platform provides a more nimble, flexible and maintainable foundation, creating greater scope to evolve quickly in response to future clinical, research, regulatory and security needs.

Several new features have been introduced to improve administrative burden, improve usability and support more efficient day-to-day data entry and follow-up management.

1. The home page has been redesigned with clearer visual indicators, making it easier, and more accessible, for users to identify outstanding tasks requiring attention.
2. A new "Recent Patients" section has been added, allowing quick access to patient records viewed recently.
3. Quick access to consent forms on the patient summary page alongside colour-coded follow-up statuses, with follow-ups appearing in red when overdue, yellow when queried, and green once verified.
4. Search tables have been added for patients' previous therapies through the "existing drug entries" tab, as well as more accessible dose delay boxes, and the ability for clinicians to enter a DLQI score without requiring a full breakdown.
5. Print toggles have also been added to the patient summary and patient history pages, allowing users to print only the information they need rather than entire pages.
6. Centre-specific statistical graphs, giving sites clearer visibility of follow-ups, data queries, PASI scores, and DLQI data; this information will improve local oversight to support data quality and completeness in the register.
7. The login page now requires an email address rather than a username, while two-factor authentication remains in place to maintain security standards.
8. A new "Report an Issue" button has also been added specifically for reporting software or website-related issues, allowing users to notify the Software Development Team quickly when issues arise.



Training Centre screenshot

The redevelopment of BADBIR's Clinicians' Web System has been a substantial undertaking by our small, dedicated Software Development Team, recognising early the need for change and driving a complete architectural redesign while maintaining a familiar user experience and a seamless transition. Colleagues across BADBIR supported the maturity of the system through early phases, carrying out extensive testing of the Clinicians' Web System, providing feedback and validation. A particularly important part of this work involved transitioning consent information into a cleaner and more consistent structure, creating a stronger foundation for future improvements such as reduced friction in patient registration, better integration with the patient portal, electronic consent, and clearer oversight of patient activity for clinicians. Ongoing feedback from all users continues to support further improvements, refining the end user experience. The legacy system will be fully retired in Summer 2026 after 14 years of service.

To support centres transitioning to the new BADBIR Web System for Clinicians, training sessions were held to introduce users to the updated Clinicians' Web System and provide opportunities for questions and feedback. The feedback from clinicians and research teams has been very positive. Our Data Processing Team are also currently developing training videos to further support users, with these resources expected to be released soon.

Earlier this year, the BADBIR website at **www.badbir.org** was also refreshed. It is a public website for patients, clinicians, researchers, governance teams and other visitors seeking information about the study. This is separate from the secure BADBIR Web System for clinicians. Improvements have focused on clearer navigation, better readability and stronger accessibility.

This project has involved significant planning, collaboration, and ongoing work across the whole BADBIR team. We would like to thank all centres for their patience, support, and feedback throughout the transition and hope the new BADBIR Web System for Clinicians and public website will continue to improve and streamline the way centres manage follow-ups and contribute data to BADBIR in the years ahead.

Hassan Ali
BADBIR Software Development Team Leader

Ollie Steer
Research Software Engineer

Statement from Rose Mennell
Data and Pharmacovigilance Administrator, BADBIR

Over the past year, I have had the pleasure of collaborating with the Database Team to help organise and participate in testing for the new BADBIR database. Thanks to the team's hard work, a robust new database was successfully launched in February 2026.

Throughout 2025, we tested and refined the database to make sure each area worked as intended. On a day-to-day basis, our team reviewed different sections, reported issues to the Database Team, and retested them once fixes had been made to confirm they were working properly.

Because the new database was built closely around the legacy system, the transition felt smooth. Many familiar features were retained, alongside useful improvements such as the ability to enter score-only DLQIs.

We hope you have found the transition to the new database to be seamless and that the new features have been helpful. Thank you for sharing feedback and reporting issues along the way, which has helped us continue to improve the system for all users.

We welcome any feedback on the new BADBIR database **please contact us via BADBIR@manchester.ac.uk**

Profiles **spotlight**

The team at NHS Lothian share their thoughts on their positive re-engagement with BADBIR

When the dermatology research nursing team was fully re-established in 2025, one of our key priorities was to re-engage with the BADBIR study and address the significant backlog of outstanding follow-up data that had accumulated over previous years.

Addressing the BADBIR backlog has required a great deal of commitment from the team alongside our routine clinical and research responsibilities. To ensure consistent progress, we allocated dedicated time within our weekly schedules to focus specifically on BADBIR activities. Through a structured approach to patient follow-up and data entry, we have been able to make substantial progress in reducing the number of overdue patients.

> *"The support and guidance provided by the BADBIR team have been invaluable in helping us develop effective processes and maintain momentum. We are very proud of what has been achieved so far and of the teamwork that has made this progress possible."*

As we work towards clearing the remaining backlog, we are looking forward to the next phase of the study which will involve re-engaging with patients in clinic for face-to-face follow-up visits. Once these processes are fully re-established, we are excited to begin recruiting patients again and contributing to the ongoing success of the study.

Lauren Finlayson, Lead Research Nurse at NHS Borders, reflects on successfully reopening the BADBIR study at the Borders General Hospital

Reopening the BADBIR study at the Borders General Hospital has been a positive step for us by giving our patients increased opportunities to participate in dermatology research.

As a small health board with an even smaller research team with only two research nurses covering all specialties, this has been a significant undertaking! However, one I believe we have managed well despite the study previously being suspended.

Taking on the role of Nurse Principal Investigator for the first time for this study has been an invaluable and surprisingly enjoyable experience. Completing the first Scottish cohort of the Principal Investigator Pipeline Programme continued to strengthen my confidence and consolidated my knowledge needed for this role.

However, none of this progress would have been possible without the commitment and support of the wider team. Specifically our research nurse, Nikki, has been fundamental to the smooth running of the study. Her work in managing follow ups, entering data, and ensuring prompt reporting of adverse events has been exceptional. Despite not having a dermatology background, she has supported the study brilliantly and is a Nurse PI herself on another study.

We have also benefited enormously from the expertise of the dermatology team, particularly our systemic/biologics specialist nurse, Fiona. Her support with the patients and her consistently-detailed clinic letters have been essential in enabling accurate and timely follow up.

This has very much been a collective effort and I believe our ability to deliver high quality research in a small board is a direct reflection of the dedication and adaptability of the staff members involved. With this strong foundation I am hopeful that we are now back on the right trajectory and will continue to see our recruitment numbers grow.

Centre Recognition **Awards**

The BADBIR Centre Recognition Awards celebrate the outstanding contributions demonstrated by participating centres across the BADBIR study, such as reducing follow-up backlogs, increasing patient recruitment and responding proactively to data queries and requests.

Centres may be nominated either by colleagues within their own teams or by members of the BADBIR team. The following centres have been nominated for this year's BADBIR Recognition Awardsin recognition of their valuable contributions to the ongoing success of the study.

Salford Royal NHS Foundation Trust

"We would like to express our sincere appreciation for this recognition. Thank you for acknowledging the dedication and hard work that has gone into achieving a significant reduction of the outstanding BADBIR follow-ups. This reflects outstanding teamwork and collaboration".

The Salford team

Doncaster and Bassetlaw NHS Foundation Trust

"We have a dedicated research clinic twice a month where patients are seen by research nurses and can complete questionnaires at the same time as their follow-up.

We track all upcoming follow-ups so patients get booked in a timely manner and do not miss their follow-up appointments which are coordinated to match their BADBIR follow-up appointments.

We have a regular reminder at monthly departmental meetings for all clinicians to send information to Dr Desai if any patient starts systemic or biologic treatment for their psoriasis.

Our dedicated pharmacist emails a list of all patients who are newly commenced on any biologic to the BADBIR research team for enrolment onto the study.

If any patient misses a BADBIR appointment I contact them to complete the BADBIR proforma either via telephone or F2F."

Dr Desai

NHS Fife

Caitlin Thomson

"We are so touched to receive this recognition. BADBIR uptake within our department unfortunately was not continued beyond the Covid pandemic. Thankfully we resumed in 2025 and got our records caught up. We have a commitment to excellence and hope to continue our hard work for years to come. We want to thank the BADBIR team for their ongoing help and support with this project".

The NHS Fife team

East Kent NHS Foundation Trust

"We are a small team in East Kent and BADBIR work is carried out only by one consultant and a registrar due to geographical challenges and a large area covered by the Trust. Despite lack of staff, we have managed to keep BADBIR going as we understand the importance of monitoring new drugs and emerging trends of efficacy and side effects. We have an active research team, the paperwork is put in notes before clinic, our outpatient nursing team gives out the paperwork beforehand and research sits in well with our biologics clinic. We have meetings to iron out any glitches and queries are answered promptly. We have managed to get a few patients to use the online tool too. Team work makes the dream work!"

Dr Rajeev

Kings college London & Kings Beckenham Beacon

"We would like to express our sincere appreciation for this recognition. Thank you for acknowledging the dedication and hard work that has gone into achieving a significant reduction of the outstanding BADBIR follow-ups. This reflects outstanding teamwork and collaboration".

The KCL & KBB team

Patient Portal

The BADBIR Patient Portal can help to reduce the workload of BADBIR.

Patients are able to complete their questionnaires online or via the App rather than completing them on paper in the clinic.

As we are unable to contact patients directly the Patient Portal will need to be promoted to the patients by a member of staff at your hospital. Once a patient is registered with the Portal they will get an email reminder from BADBIR when their next follow-up is due to complete their questionnaires.

If a patient doesn't wish to complete questionnaires please ask if patient would still be willing for their clinical data to be collected so that important safety data can continue to be collected.

How do Participants use the Portal?

Patients can access the Portal via the BADBIR website (**www.badbir.org**) and can create an account using details already known to them:

- NHS Number (or BADBIR Study ID Number)
- Date of Birth
- First and Last Initials

Newly registered patients can complete their baseline questionnaires through the Portal once they are entered onto the database by the clinical research team.

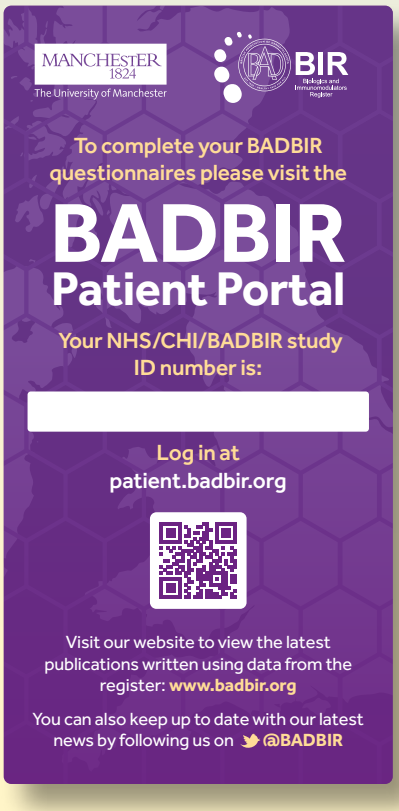
How do I inform patients of the Portal?

You are allowed to contact patients outside of their normal appointments to invite them to use the Portal. A BADBIR non-substantial amendment was approved on 15/07/2021 allowing you to make this contact.

You can contact patients however you wish (e.g. letter, phone, email, etc.) and advise them that more information is available on the BADBIR website on how to register and use the Portal.

We have a handout which can be given to the patient in clinic (picture 1). The BADBIR substantial amendment 13 which was approved on 19/01/2023 included an invitation letter for the Patient Portal which you can send to the patients in the post. The approval of this invitation letter allows reasonable changes to reflect your local practice.

Picture 1



Can all patients use the portal?

The amendment which was approved 19/01/2023 altered the study design to allow patient questionnaires to be completed at every follow-up.

Any data entered in the Patient Portal is automatically placed into the most appropriate follow-up based on the date it was completed.

Will Participants be Reminded When to Enter Questionnaire Data?

Patients who are set-up on the Portal will receive an email prompt when their next questionnaires are due and receive reminder emails if the questionnaires were not completed after the first prompt.

Where Can I Find More Information on the BADBIR Portal?

Further information about the Portal is available on the BADBIR website (**www.badbir.org**). The BADBIR team can also be contacted directly with any queries on **badbir@manchester.ac.uk** or **0161 306 1896**.

Save time in clinic by using the BADBIR Patient Portal

- **No need to print questionnaires for patients complete**
- **No data entry required – patient responses are saved directly into the BADBIR database**
- **Participants will be prompted automatically when questionnaires are due**
- **Time required to file, scan or archive questionnaires is not needed with the Portal**

Associate Principal Investigator **Scheme**

The Associate Principal Investigator (API) scheme aims to develop health and care professionals to become the Principal Investigators (PIs) of the future.

It is a six month in-work training opportunity, providing practical experience for healthcare professionals starting their research career and who would not normally take part in clinical research in their day-to-day role.

This means that Associate Principal Investigators can experience working on and delivering an NIHR portfolio trial under the mentorship of an enthusiastic local PI.

Those completing the scheme receive formal recognition of their engagement in NIHR Portfolio research studies via certification of Associate PI status, endorsed by the NIHR and Royal Colleges.

To find out more and to apply to become an Associate PI please visit the NIHR website.

Dr Amany Dawoud, based at Sherwood Forest Hospitals NHS Foundation Trust, has recently completed the API scheme and shared her thoughts:

"I was fortunate to be placed on the BADBIR study. Working on a nationally-recognised study of this scale, within my own specialty, felt deeply relevant and meaningful. One of the most eye-opening aspects of the scheme was seeing how research actually works — not in textbooks, but in the reality of a busy NHS dermatology department.

> ***I was fortunate to be placed on the BADBIR study. Working on a nationally-recognised study of this scale, within my own specialty, felt deeply relevant and meaningful.***

I learned about delegation logs, eligibility screening, patient information materials, steps of consenting patients and the BADBIR database. What struck me most was how much research depends on relationships. The collaboration between the clinical team and the research team is what makes studies like BADBIR possible, and I gained a genuine appreciation of that partnership.

To be honest, the scheme is not without its challenges. Fitting research activity around clinical commitments is genuinely difficult. Clinic slots are short, patients are complex, and there is always another task competing for your attention. Now I have a new-found respect and appreciation for colleagues who sustain research activity over years alongside demanding clinical roles.

I came into this scheme as a clinician who was curious about research. I leave it as a clinician who is committed to it. I am grateful to the onsite BADBIR team, to my local PI and the national study team for their support and encouragement throughout. The scheme gave me the foundations, and I'm looking forward to future opportunities to take on greater responsibility."

Dr Liang Zhi Wong of Whittington Health NHS Trust also recently completed the API scheme:

Serving as an Associate Principle Investigator for BADBIR has been an extremely rewarding research experience for me. The scheme provided a unique opportunity to contribute to a national clinical trial while helping develop my practical skills in patient recruitment, research governance and study delivery within routine clinical practice.

Working alongside clinical research practitioners and dermatology registrars on this has helped me gain a deeper understanding of how data is being collected and synthesized in contribution to growing the BADBIR registry.

Through my involvement with BADBIR, I recruited patients, supported data collection, collaborated with the wider Multidisciplinary Team and liaised with the central BADBIR committee to troubleshoot problems. This has strengthened my confidence in engaging patients with research and balancing research activities alongside routine clinical practice.

I am grateful for the experience and opportunities provided through BADBIR and would strongly encourage trainees and junior doctors interested in dermatology research to participate in the BADBIR API programme!"

Key **Publications**

Scan to see a full list of our publications

Using biologic therapies as first-line systemic treatment for psoriasis: A cohort study following the target trial emulation framework from the British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR).

Duc Binh Phan

Duc Binh Phan[1]; Philip Laws[2]; Catherine H. Smith[3]; Christopher E. M. Griffiths[1,4]; Brian Kirby[5]; Olivia Hughes[6]; Gabriel Rogers[7]; Oras A. Alabas[1]; Mark Lunt[8]; Richard B. Warren1; Zenas Z. N. Yiu[1].

Questions

rrent UK and Republic of Ireland treatment guidelines require patients with moderate-to-severe psoriasis to try and fail conventional systemic drugs (such as methotrexate or ciclosporin) before being prescribed biologic therapies. This stepwise approach may delay access to the most effective treatments, leading to prolonged physical and psychological burden. We asked: Does initiating biologics as first-line systemic therapy, rather than following the standard stepwise approach, lead to better clinical outcomes and fewer long-term complications over five years?

Findings

Study design and population

- We analysed real-world data from the British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR), using a target trial emulation framework.
- 3,702 adults with moderate-to-severe psoriasis (baseline PASI ≥10) who had received no prior systemic therapy were included.
- 3,368 followed the current standard of care (conventional systemic therapy first, with possible subsequent switch to biologics); 334 initiated a biologic as first-line systemic therapy.

Outcome	Standard Care (n=3,368)	Biologic First (n=334)
Mean PASI at 5 years	4.7 (95% CI 4.0–5.4)	2.0 (95% CI 1.2–2.7)
Mean DLQI at 5 years	5.6 (95% CI 4.2–7.0)	3.5 (95% CI 1.3–5.7)
Complete skin clearance (PASI 0)	32.2%	58.6%
Cumulative comorbidity risk	54.3%	47.5%

- Participants were followed for up to five years.

Key results

The table above summarises the primary outcomes at five years:

Disease severity and quality of life (PASI and DLQI) at 5 years:

- At five years, patients who started biologics first had a mean PASI of 2.0 (95% CI 1.2–2.7) compared with 4.7 (95% CI 4.0–5.4) for standard care.
- Quality of life (DLQI) was also better in the biologic-first group: 3.5 (95% CI 1.3–5.7) versus 5.6 (95% CI 4.2–7.0).

Complete skin clearance

- Biologic-first patients were significantly more likely to achieve complete skin clearance (PASI 0): 58.6% vs 32.2% in the standard care group.
- The hazard ratio for achieving PASI 0 was 2.85 (95% CI 2.34–3.47), meaning biologic-first patients were significantly more likely to reach complete clearance at any given time point.

Long-term comorbidities

- The cumulative risk of developing a new long-term comorbidity over five years was lower in the biologic-first group: 47.5% vs 54.3% (HR 0.72, 95% CI 0.58–0.89).
- Mental health disorders: biologic-first patients had a 36% lower risk of developing a new mental health condition (HR 0.64, 95% CI 0.44–0.94).
- Hepatic (liver) disorders: a 46% lower risk was observed in the biologic-first group (HR 0.54, 95% CI 0.38–0.76).

Meaning

These findings demonstrate that initiating biologics as first-line systemic therapy is associated with substantially better clinical and quality-of-life outcomes compared with the standard stepwise approach. Patients treated with biologics first achieved nearly twice the rate of complete skin clearance, sustained lower disease severity, and were significantly less likely to develop mental health and liver complications over the following five years.

With the growing availability of lower-cost biosimilar biologics, the cost barrier to earlier use is diminishing. These results support reconsideration of existing treatment pathways in the UK and Republic of Ireland to allow earlier access to biologic therapies for patients with moderate-to-severe psoriasis.

Author Affiliations

1. Dermatology Centre, Northern Care Alliance NHS Foundation Trust & Division of Musculoskeletal and Dermatological Sciences, Manchester NIHR Biomedical Research Centre, Manchester Academic Health Science Centre, University of Manchester, Manchester, United Kingdom.
2. Department of Dermatology, University of Leeds, Leeds, United Kingdom.
3. St Johns Institute of Dermatology, Guys & St Thomas NHS Foundation Trust, Kings College London, London, United Kingdom.
4. Department of Dermatology, King's College Hospital, King's College London, London, United Kingdom.
5. St. Vincent's University Hospital and Charles Institute of Dermatology, University College Dublin, Dublin, Republic of Ireland.
6. School of Psychology, Cardiff University, Cardiff, United Kingdom.
7. Manchester Centre for Health Economics, Division of Population Health, Health Services Research & Primary Care The University of Manchester, Manchester, United Kingdom.
8. Versus Arthritis Epidemiology Unit, Division of Musculoskeletal & Dermatological Sciences, The University of Manchester, Manchester, United Kingdom.

Adalimumab Monotherapy vs Adalimumab With Methotrexate for Psoriasis

Dr Zenas Yiu et al., JAMA Dermatology, 2025

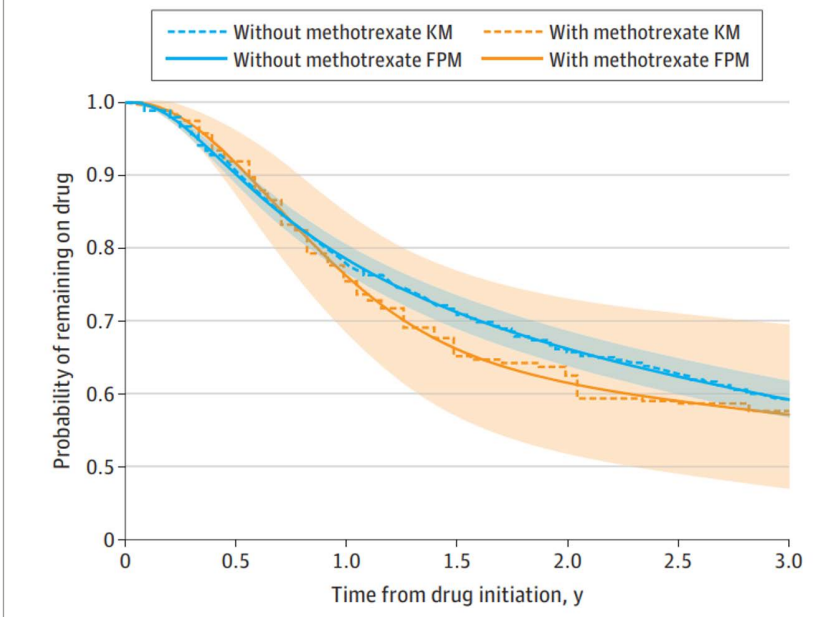
What did we do?

We studied whether combining two medicines—adalimumab and methotrexate—would lead to better treatment outcomes in people with moderate-to-severe plaque psoriasis. Adalimumab is a commonly used biologic therapy that targets inflammation, while methotrexate is a traditional immune-suppressing drug that is often used in combination with biologics in other autoimmune diseases like rheumatoid arthritis. In those conditions, combination therapy has been shown to improve treatment effectiveness and reduce the chances of the body developing resistance to the biologic drug. However, there is limited evidence to support this approach in psoriasis.

To find out more, we analysed data from people in the UK who had recently started treatment with adalimumab, either alone or together with methotrexate. We tracked how well their skin symptoms improved over time and whether there were any differences in how long people stayed on treatment or in the number of side effects experienced.

What did we find?

We found that adding methotrexate to adalimumab did not lead to significantly better outcomes. Both groups—those on adalimumab alone and those on combination therapy—showed similar improvements in skin clearance over time. There were also no meaningful differences in how long people remained on treatment (known as drug survival), nor in how often treatment was discontinued. Side effects appeared similar across both groups.



Weighted Kaplan-Meier (KM) dotted line overlaid with the flexible parametric (FPM) standardized survival curve (solid line) for the monotherapy and methotrexate arms. Shaded areas represent 95% CIs.

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This suggests that, unlike in some other immune conditions, methotrexate does not seem to enhance the effectiveness of adalimumab in psoriasis. The results were consistent across different measures of skin improvement and were based on real-world clinical practice, not just clinical trials.

What does this mean for people with psoriasis?

For people living with moderate-to-severe plaque psoriasis, this study suggests that taking adalimumab on its own is just as effective as taking it with methotrexate. This is important because methotrexate can carry additional risks, such as liver toxicity or the need for regular blood monitoring, and some people may find it difficult to tolerate.

The findings offer reassurance that most people with psoriasis can benefit from biologic treatment with adalimumab without needing to add another drug. This simplifies treatment, potentially reduces the risk of side effects, and lessens the burden of taking multiple medications. However, everyone responds differently, and treatment should always be tailored to each individual. Some patients may still benefit from combination therapy based on their personal circumstances, and decisions should be made together with a healthcare provider.

Serious infection risk in **patients receiving systemic treatments for psoriasis**

Introduction

Serious infections remain a key safety concern for patients receiving systemic treatments for psoriasis, particularly due to the immunomodulatory effects of biologics. Certain older biologics have been associated with an increased serious infection risk. However, with the wider use of newer biologics such as IL-17 and 23 inhibitors, there is a need to reassess this risk using more comprehensive and contemporary data. Moreover, prior studies were limited to evaluating only the first occurrence of serious infection.

Question

Do systemic treatments for psoriasis differ in their risk of serious infection when compared with each other?

Findings

This study analysed 46,770 treatment episodes from 18,976 adults with confirmed psoriasis who received systemic treatments for at least 6 months. The overall incidence of serious infection was observed to be low at 27.67 events per 1000 person-years (95% CI, 26.72 to 28.65). No significant differences in serious infection risk were observed across most treatments. However, risankizumab was associated with a slightly lower risk compared with brodalumab (HR 0.74; 95% CI 0.55 to 0.99), etanercept (HR 0.75; 95% CI 0.60 to 0.94) and standard treatments (HR 0.80; 95% CI 0.65 to 0.98). Although IL-23 inhibitors showed numerically lower hazard ratios, no significant class effects were identified in the group comparisons (Figure 1). Mortality within 30 days of a serious infection was rare (1.81 deaths per 1000 person years). Following a serious infection event, 67.8% of patients continued treatment for at least 90 days, 18.2% discontinued, 10.0% switched treatments, and 4.0% postponed treatment.

Meaning

These findings suggest that biologic treatments have broadly comparable safety profiles with respect to serious infection risk. While risankizumab was associated with a statistically significant lower risk, the clinical relevance of this difference should be interpreted with caution given the low overall incidence. Overall, the results support treatment decisions based on patient characteristics, with risankizumab offering a potential option for patients concerned about serious infection risk.

Figure 1: **League table of serious infection risk estimates from recurrent event analysis for the psoriasis treatment group comparisons**

	Apremilast	Conventional	Il_12_23_inhibitor	Il_17_inhibitors	Il_23_inhibitors	Tnf_inhibitors
Apremilast	NA	0.92 (0.51–1.64)	0.87 (0.50–1.51)	1.04 (0.64–1.71)	0.70 (0.22–2.20)	1.14 (0.69–1.88)
Conventional	1.09 (0.61–1.95)	NA	0.95 (0.65–1.37)	1.14 (0.74–1.74)	0.76 (0.26–2.25)	1.24 (0.90–1.73)
Il_12_23_inhibitor	1.15 (0.66–1.99)	1.05 (0.73–1.53)	NA	1.20 (0.81–1.78)	0.81 (0.27–2.37)	1.31 (0.97–1.78)
Il_17_inhibitors	0.96 (0.59–1.57)	0.88 (0.57–1.35)	0.84 (0.56–1.24)	NA	0.67 (0.24–1.89)	1.10 (0.77–1.55)
Il_23_inhibitors	1.43 (0.45–4.48)	1.31 (0.44–3.86)	1.24 (0.42–3.64)	1.49 (0.53–4.17)	NA	1.63 (0.57–4.69)
Tnf_inhibitors	0.88 (0.53–1.44)	0.80 (0.58–1.12)	0.76 (0.56–1.03)	0.91 (0.64–1.29)	0.61 (0.21–1.77)	NA

Hazard ratios with 95% confidence intervals for each systemic treatment compared to each other are presented. Reference drugs are shown in the rows, and comparator drugs are listed in the columns. Each cell displays the hazard ratio for the comparator drug relative to the reference drug. The blue color indicates reduced risk; red indicates increased risk and white indicates estimates close to null effect. Cells with statistically significantly lower risks are highlighted with blue borders, whereas cells with statistically significantly higher risks are highlighted with red borders.

Upcoming **Research Highlights**

Dr Oras Alabas
BADBIR Research Fellow

Over the last year, research using BADBIR data has been presented at several conferences. Ahead of full publication, here are some key messages from recent abstracts:

Cancer

Evidence on the risk of cancer associated with biologic therapies for psoriasis remains limited, and findings from previous studies have been inconsistent. While some studies have reported an increased risk of cancer among patients treated with biologics, others have found no association. These conflicting findings may be explained by factors such as small sample sizes, short follow-up periods, use of different combination therapies, differences in psoriasis severity between study groups, and methodological limitations, including variations in confounder adjustment and statistical approaches.

The aim of this study was to assess the real-world risk of developing cancer (defined as cancer overall excluding keratinocyte carcinoma [KC]) or KC among patients with psoriasis receiving biologic therapy. The study population included biologic-naïve patients with chronic plaque psoriasis enrolled in BADBIR between 2007 and 2025, aged 16 years or older, who were receiving systemic treatment for psoriasis and had no history of cancer at registration. BADBIR data were linked with NHS Digital databases to improve the identification of cancer events. Propensity score-weighted flexible parametric survival models were used to estimate adjusted hazard ratios for each outcome. Our findings showed no increased risk of cancer or KC among patients treated with biologics compared with those receiving non-biologic systemic therapies. Similarly, no increased risk of cancer or KC was observed when comparing interleukin (IL)-12/23 inhibitors (i) or IL-17i with tumour necrosis factor inhibitors (TNFi). This large real-world study provides reassuring evidence that the risks of cancer and KC do not differ between biologic and non-biologic systemic therapies, nor across biologic classes. This work was presented as an oral presentation at the BAD Annual Meeting in July 2025.

Pregnancy

Pregnancy outcomes are an important consideration when managing women of childbearing age with moderate-to-severe psoriasis. However, few registries collect data on the safety of systemic treatments during pregnancy, and women who are pregnant or planning conception are typically excluded from clinical trials. To address this evidence gap, an abstract entitled "Pregnancy-Related Outcomes in Women with Moderate-to-Severe Psoriasis: Analysis from the British Association of Dermatologists Biologic and Immunomodulators Register (BADBIR)" was presented as an oral presentation at the EADV Congress in Paris in September 2025. The aim of this study was to describe pregnancy-related outcomes in women with psoriasis receiving systemic therapies. The study population included women aged 16-47 years with moderate-to-severe psoriasis who were enrolled in BADBIR between September 2007 and April 2025, were receiving either non-biologic systemic therapy or biologic therapy at enrolment, and had known pregnancy outcomes. Outcomes of interest included live birth, miscarriage, elective abortion, pregnancy complications, labour complications, post-partum complications, and fetal abnormalities.

Our results showed that the incidence proportions of pregnancy-related outcomes, with corresponding 95% confidence intervals, were broadly similar across treatment groups. During the early period of BADBIR enrolment (2007–2014), Humira was the most commonly prescribed biologic among pregnant women, followed by Stelara and Cimzia. However, prescribing patterns changed during the later enrolment period (2015–2025), with Cimzia becoming the most commonly prescribed biologic, followed by Stelara and Humira.

When selected pregnancy-related outcomes were compared with those reported in the general populations of England and Wales, similar proportions of live births, abortions, and fetal abnormalities were observed. Overall, these real-world data suggest that pregnancy-related outcomes in women with moderate-to-severe psoriasis were similar across treatment groups and broadly comparable to those reported in England and Wales.

Incident Psoriatic Arthritis

Psoriatic arthritis (PsA) affects approximately 20% of individuals with psoriasis and can have a substantial impact on quality of life. The aim of this study – presented most recently at the 2026 British Society for Investigative Dermatology (BSID) Annual Meeting - was to investigate the risk of developing PsA among patients receiving different biologic therapies for psoriasis.

The study population included individuals aged 16 years or older with chronic plaque psoriasis who were biologic-naïve, initiated their first biologic therapy as monotherapy, and had no recorded history of PsA prior to enrolment in BADBIR. Data from patients enrolled between September 2007 and November 2025 were analysed. Propensity score-weighted flexible parametric survival models were used to estimate the risk of developing PsA.

Our findings showed that, among biologic classes, the risk of developing PsA was significantly lower in patients treated with IL-23 inhibitors (i) compared with tumour necrosis factor inhibitors (TNFi). However, no significant differences in PsA risk were observed for IL-12/23i or IL-17i compared with TNFi. These findings suggest that IL-23i may be associated with a lower risk of developing PsA compared with TNFi, while the risks associated with IL-12/23i and IL-17i appear comparable to TNFi. Further studies with larger sample sizes and longer follow-up, especially for the newer biologics, are needed to confirm these results.

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