

# BADBIR

## Annual Update

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**Monitoring the  
long-term safety  
of new treatments  
for psoriasis.**



# Welcome

Welcome to the 2024 BADBIR Update. Led by the British Association of Dermatologists and co-ordinated at the University of Manchester, since 2007 BADBIR has grown to be a leading source of real-world data for researching psoriasis therapies.



This has taken remarkable collective effort at dermatology departments across the UK and Eire to continue to build on the success of this observational register. All data recorded at sites contributes significantly to answering clinically important questions on safety and treatment selection, helping strengthen reassurance for patients and prescribers using systemic treatments for psoriasis.

## A Continued Success

Later in this update, we will report on some of the key statistics following 17 years of data collection. Now with over 22,000 participants now registered, BADBIR continues to grow each year not just in recruitment but also follow-up data adds to the available Person Years powering pharmacovigilance and other research objectives. The scope and scale of the Register has made it the largest such psoriasis project of its kind globally. The successful alliance of the BAD and the pharmaceutical industry in commissioning BADBIR has helped set a precedent for how real-world data studies can be embedded in a clinic setting and ultimately inform practice. This model has influenced similar projects including ASTAR for atopic dermatitis and GRASS-UK for alopecia.

## High Quality Research

The dedicated contributions from research teams across the UK and Ireland have fuelled a growing number of publications using BADBIR data. At time of writing, there are 42 articles in scientific journals (listed in full on

the final page of this update). Current research questions are documented in subsequent sections and summaries of publications including the Risk of Paradoxical Eczema in patients receiving Biologics for Psoriasis. The breadth of research topics currently underway demonstrates the power of the dataset accrued in addressing a wide range of questions. Data from BADBIR is constantly reaching greater maturity and there are still plenty of unexplored research questions. The data is available to access for this purpose, and I encourage anyone with a research-interest in psoriasis to explore this further. Please visit [www.badbir.org/Publications/DataAccess](http://www.badbir.org/Publications/DataAccess) for full details.

## Looking Forwards

To continue the success of the BADBIR, we are grateful to sites in their efforts to maintain accurate follow-up on all patients. We are very encouraged by all the hard work to keep the Register up to date with the vast majority of sites open and actively contributing. The study team in Manchester are available to support sites with their follow-ups. We can provide training for efficiently recording all follow-up data and avoiding data queries ([www.badbir.org/contact](http://www.badbir.org/contact)).

With data collection still ongoing, BADBIR continues to make changes to protocol to stay as contemporaneous as possible and relevant for clinical practice in 2024 and beyond. An example of this is the recently launched Patient Portal where participants can directly contribute their own data to the

study. The study design was amended in 2023 to allow as many participants as possible to record questionnaires including the Dermatology Life Quality Index (DLQI). This amendment also added severity measures specific to Generalised Pustular Psoriasis to ensure the study can appropriately assess effectiveness in all diagnoses covered in BADBIR. The available psoriasis therapies continue to expand, BADBIR will also aim to capture information on any new small molecule products, and biosimilars as they reach the NHS in the coming year.

## Thank you

To close we must thank the Principal Investigators and Research Teams who have dedicated so much time and effort to building such an impressive resource. Particular thanks go to the thousands of patients who have kindly agreed for their progress on new psoriasis treatments to be followed over the last 17 years. There is evident value in the outputs from BADBIR to date and we look forward to collaboratively adding further evidence for patients and clinicians for many years to come.

**Professor Richard Warren,  
BADBIR Chief Investigator**

# Meet the Team

Colleagues from the BADBIR co-ordinating centre based at The University of Manchester

## Study Managers



Kathy McElhone



Danielle Bowerbank



Sam Pacynko



Shamila Irshad



Victoria Wilde



Saliha Tahir

## Pharmacovigilance Team

## Centre Support Team



Aneisha Ahmed



Kerry Williams



Oras Alabas



Adele Moores

## Research Fellow

## Finance Administrator

## Data Processing Team

## Database Team



Yoana Petrova



Rose Mennell



Tegan Galbraith



Ollie Steer



Hassan Ali

Colleagues based at The British Association of Dermatologists



Shehnaz Ahmed  
Director of Research and Publishing



Joy Read  
Research Coordinator



Zin Mon  
Research Manager

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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.

**22,163** total registrations 

**15,416**  
in Biologic Cohort

**6,326**  
in the Conventional Comparison Cohort

**421**  
in the Small molecule Cohort

**155,034**  
Follow-up Visits recorded on BADBIR

**209,293**  
PASIs collected

**100,620**  
DLQIs completed

**109,419**  
Adverse events entered

**168 centres**  
have recruited to BADBIR

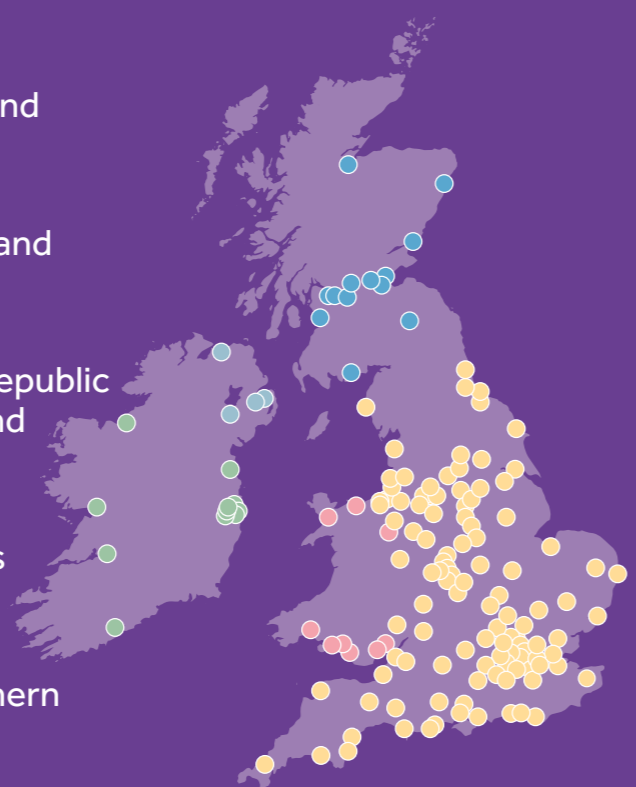
**131**  
in England

**13**  
in Scotland

**11**  
in the Republic of Ireland

**9**  
in Wales

**4**  
in Northern Ireland



**42** Journal Articles Published Using Data from BADBIR

Data held on **33** Different Systemic Treatments for Psoriasis

# Eligibility



## Eligibility Criteria

The British Association of Dermatologists (BAD) recommend that **all psoriasis patients** in the UK should be registered with us. The following is our eligibility criteria.



**Chronic plaque or generalised pustular psoriasis**



**Written informed consent**



**Under care of a dermatologist**

## Treatments

Patients must be **starting** or **switching to** one of these drugs, **for treatment of their psoriasis**, in the **last 6 months** to be eligible:



### CONVENTIONAL

- ✓ Acitretin
- ✓ Ciclosporin
- ✓ Fumaric acid esters
- ✓ Hydroxycarbamide
- ✓ Methotrexate
- ✓ Systemic oral PUVA

### BIOLOGIC

- ✓ 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

- ✓ Sotyktu (deucravacitinib)
- If a patient has prior exposure to biologic and starting Sotyktu they will enter the biologic exposed cohort.

## PASI and DLQI



Conventional patients must have a **PASI of 10 or more** and a **DLQI of 11 or more** (unless switching between conventional therapies). There is no minimum score for biologic or small molecule patients (but we still require a PASI and DLQI).

Patients entering either the small molecule or conventional cohorts must be naive to biologic therapy.

## Paediatric Patients



If the patient is **under the age of 16 at the time of consent**, and starting any **systemic treatment for psoriasis**, the patient will be eligible for BADBIR. Conventional patients **do not** need to meet the cDLQI score criteria



# 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](http://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.

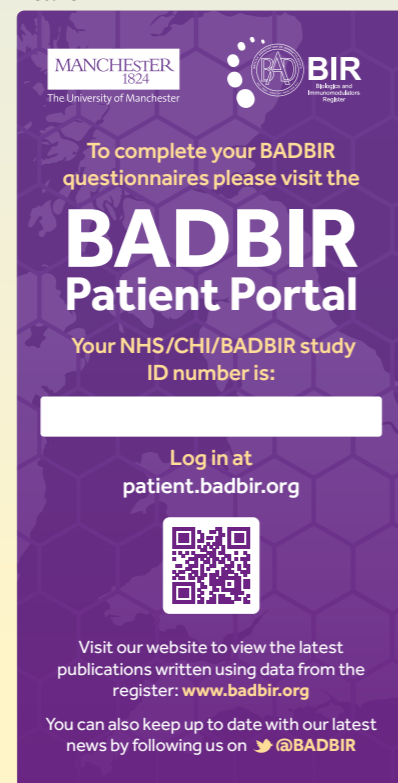
## How do I inform patients of the Portal?

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](http://www.badbir.org)). The BADBIR team can also be contacted directly with any queries on [badbir@manchester.ac.uk](mailto: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 scheme aims to develop health and care professionals to become the Principal Investigators of the future

## What is the Associate Principal Investigators scheme?

It is a six month in-work training opportunity, providing practical experience for healthcare professionals starting their research career.

People who would not normally have the opportunity to take part in clinical research in their day-to-day role have the chance to experience what it means to work on and deliver an NIHR portfolio trial under the mentorship of an enthusiastic Local Principal Investigator (PI).

Associate Principal Investigators receive formal recognition of engagement in NIHR Portfolio research studies through the certification of Associate PI status, endorsed by the NIHR and Royal Colleges.

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

Hear from those who have completed the scheme.

**Hamisha Salih**  
University Hospitals  
Sussex NHS  
Foundation Trust



The Associate Principal Investigator role on the BADBIR study has been an invaluable opportunity to gain research experience. Under the mentorship of my local PI, the role has allowed me to gain practical experience in delivering research and develop an understanding of what is involved in conducting clinical trials. BADBIR has been a great study for this role as I have been able to engage in every step of the patient pathway and significantly contribute to the running of the study at our site. This hands-on experience, along with the NIHR API courses, has been a hugely beneficial experience to equip me with the skills to pursue a PI role in the future and I would highly recommend it to anyone keen to get involved in research.

**Anna Nielsen-Scott**  
University Hospitals  
Sussex NHS  
Foundation Trust



The NIHR associate PI scheme has been an amazing opportunity to develop my understanding of clinical research. It offers an important stepping stone for working as a Principal Investigator in the future.

The platform and resources are easy to navigate. The program itself is not excessively time-consuming, meaning successful completion can easily fit around other clinical activities. Thank you!

**Mohanad Aldiwani**  
University Hospitals of  
Leicester NHS Trust



## Positive Points

1. The scheme is a great opportunity to give more insight about research and the available trials across the UK.
2. It will help the dermatology trainees to build up their skills and knowledge about different aspect of research such as the aim of the trials, methodology, recruitment process, eligibility etc.
3. Being an API has made me aware about the challenges we may face in research such as time pressure, resources, staffing etc. this is true in busy dermatology centres across the UK.
4. A great opportunity to for the trainees to enhance communications with research team in the region and act as a link between the local Research team and the regional /national team.
5. The Scheme will prepare research minded trainees to step up and take PI role in their trust.

## Challenges

1. Time pressure during clinical work, it a bit tough to recruit patients directly from the clinic where we have 15-minute slots.
2. Patient willingness to engage in research.

STUDY SUMMARY

# Adalimumab Biosimilars for Psoriasis Treatment

**Duc Binh Phan, is a PhD Student in Dermatological Sciences at The University of Manchester. His research aims to evaluate the use of biosimilars in the treatment of psoriasis in the UK and Republic of Ireland.**



## Introduction

Humira – adalimumab originator – is an effective but previously expensive treatment for moderate to severe psoriasis. Adalimumab biosimilars, products that are highly similar to Humira, are much cheaper and therefore offer potential cost savings in healthcare. However, because of manufacturing complexities, it is almost impossible to produce a biosimilar that is identical to Humira. Due to the extrapolation of regulatory approval from one to all indications, only a limited number of biosimilars currently available for psoriasis had their effectiveness and safety compared with Humira in psoriasis clinical trials. Real-world evidence comparing adalimumab biosimilars with Humira is also limited.

## Main summary of work

### Question

What are the differences in treatment persistence, effectiveness and safety of adalimumab biosimilars compared to that of Humira for psoriasis?

### Findings

#### Drug survival and safety of adalimumab biosimilars

First, we conducted a study using data from 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) to compare treatment persistence and safety of adalimumab biosimilars with Humira for psoriasis treatment.

We compared adalimumab-naïve patients starting biosimilars (new users) with those starting Humira, and patients switching from Humira to biosimilars (switchers) with those continuing Humira. Patients were matched 1:1 based on previous adalimumab exposure, resulting in equal-sized cohorts. Data included five biosimilars: Amgevita, Imraldi, Hyrimoz, Idacio, and Hulio.

We included 7,387 biosimilar new users and 3,654 switchers, matched with 7,387 Humira new users and 3,654 continuous users, respectively. No difference in all-cause discontinuation was found between biosimilars and Humira new users (HR: 0.99, 95% CI: 0.94 – 1.04). However, switchers had a higher discontinuation rate than continuous Humira users (HR: 1.35, 95% CI: 1.19 – 1.52). Discontinuation of biosimilars among switchers was significantly influenced by switching back to Humira or discontinuation due to skin or injection site reactions. Serious adverse events that resulted in hospitalisation or death were similar between biosimilar new users and Humira new users (IRR: 0.91, 95% CI: 0.80 – 1.05) and between switchers and continuous Humira users (IRR: 0.92, 95% CI: 0.83 – 1.01).

#### Effectiveness of adalimumab biosimilars

Second, we conducted a study using BADBIR data to emulate two targeted pragmatic randomised clinical trials (RCTs). The first RCT compared the effectiveness of initiating Amgevita or Imraldi versus Humira for psoriasis in adalimumab-naïve patients (the

new user analysis). The second RCT compared the effectiveness of switching from Humira to either Amgevita or Imraldi versus continuing Humira in patients who had used Humira for over two years (the switcher analysis).

The study outcomes were achieving a Psoriasis Area and Severity Index (PASI) of  $\leq 2$  and  $\leq 4$  at 12 months. In the new user analysis, we identified 6,133 patients (5,416 starting Humira, 382 starting Amgevita, and 335 starting Imraldi). In the switcher analysis, we included 5,267 patients (3,808 continuing Humira, 847 switching to Amgevita, and 612 switching to Imraldi).

No significant differences were found between Humira new users and Amgevita or Imraldi new users in achieving PASI $\leq 2$  (OR [95% CI]: 0.98 [0.78 – 1.25] and 0.83 [0.64 – 1.07], respectively) or PASI $\leq 4$  (OR: 1.07 [0.84 – 1.37] and 0.91 [0.69 – 1.20], respectively). Similarly, no significant differences were found for Amgevita and Imraldi switchers compared to continuous Humira users in achieving PASI $\leq 2$  (OR: 1.19 [0.94 – 1.51] and 0.92 [0.72 – 1.18], respectively) or PASI $\leq 4$  (OR: 1.32 [0.96 – 1.84] and 1.00 [0.70 – 1.41], respectively).

### Meaning

Adalimumab biosimilars showed comparable effectiveness and safety to Humira, suggesting these biosimilars could be considered alongside Humira for psoriasis. However, patients who switched from Humira to biosimilars were more likely to discontinue treatment compared to those who stayed on Humira. This result highlights the importance of physicians' and patients' communication regarding the transition from Humira to biosimilars.

STUDY SUMMARY

# Risk of Paradoxical Eczema in Patients Receiving Biologics for Psoriasis

**Dr Al-Janabi et al, JAMA Dermatol 2024**



## Meaning

This study confirmed that while paradoxical eczema can occur on any of the biologic classes used for psoriasis, IL-23 inhibitors possess the lowest risk. Based on our clinical practice, we were surprised that the incidence in IL-17 inhibitors was not even higher. We also identified that history of atopic diseases, specifically

atopic eczema or hay fever, increases the risk of paradoxical eczema. This suggests a possible genetic component to this side effect. More data is required to understand whether there is a difference between different biologic drugs within each class, and to try to accurately predict those who may develop this side effect.

## Introduction

Biologics used for psoriasis have been reported to trigger an atopic eczema reaction, or paradoxical eczema, in some patients. This can be difficult to treat, and may require stopping or switching of the biologic treatment. It is unclear which therapies are most likely to cause this, and which patients are most likely to develop this side effect.

## Main summary of work

### Question

Which biologics and risk factors increase the risk of paradoxical eczema?

### Findings

This study used data from 24,997 biologic exposures in 13,699 patients recruited to BADBIR. We found that the overall incidence of paradoxical eczema was low, but highest in drugs targeting interleukin (IL)-17, followed by tumour necrosis factor (TNF), then IL-12/23 and finally IL-23. Compared to biologics targeting tumour necrosis factor (TNF), there was a significantly lower risk with drugs targeting interleukin (IL)-23 (hazard ratio [HR] 0.39, 95% confidence interval [CI] 0.19-0.81). There was a lower risk of paradoxical eczema in males (HR 0.60, 95% CI 0.45-0.78) and a higher risk with increasing age (HR 1.02 per year, 95% CI 1.01-1.03), prior history of hay fever (OR 3.78, 95% CI 1.49-9.53) and prior history of atopic eczema (OR 12.40, 95% CI 6.97-22.06).

**Table. Propensity weight-adjusted Cox proportional hazards survival models for risk of paradoxical eczema by biologic class, biologic drug or other covariates.**

	Hazard ratio	95% CI	P-value
<b>Model 1 – biologic class (TNFi reference category)</b>			
IL-17i	1.03	0.74-1.42	0.86
IL-12/23i	0.87	0.66-1.16	0.35
IL-23i	0.39	0.19-0.81	0.01
<b>Model 2 – other baseline clinical variables</b>			
Age	1.02	1.01-1.03	0.003
Male	0.60	0.45-0.78	<0.001
Atopic dermatitis	12.40	6.97-22.06	<0.001
Asthma	0.97	0.61-1.54	0.90
Hay fever	3.78	1.49-9.53	0.005
Psoriatic arthritis	1.19	0.89-1.60	0.24
Erythrodermic psoriasis	1.10	0.76-1.59	0.60
Generalised pustular psoriasis	0.83	0.43-1.59	0.58
Palmoplantar pustulosis	1.13	0.52-2.45	0.75

# Principal Investigators

Thank you to the Principal Investigators and their teams at all the centres who contribute their time and effort to BADBIR. It is the ongoing hard work and commitment of these teams which helps continue the success of the Register.

Accurate on 24/06/2024. Note: some centres do not have a current principal investigator listed.

Aneurin Bevan Health Board  
**Dr Nabil Ponnambath**

Ashford and St Peters NHS trust  
**Dr Annabel Scott**

Barnsley Hospitals NHS Trust  
**Mrs Jill Ramsay**

Barts Health NHS Trust (Barts)  
**Dr Maria Angeliki Gkini and Dr Bryan McDonald**

Barts Health NHS Trust (Whipps Cross)  
**Dr Anthony Bewley**

Bedfordshire Hospitals  
NHS Foundation Trust (Bedford)  
**Dr Ekaterina Burova**

Bedfordshire Hospitals NHS Foundation Trust  
(Luton & Dunstable)  
**Dr Bernadette De Silva**

Belfast Health & Social Care Trust  
**Dr Kevin McKenna**

Betsi Cadwaladr University Health Board  
(Glan Clwyd)  
**Dr Diane Williamson**

Betsi Cadwaladr University Health Board  
(Wrexham Maelor)  
**Dr Periasamy Balasubramaniam**

Betsi Cadwaladr University Health Board  
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**Dr Fiona Antony**

Gloucestershire Hospitals NHS Foundation Trust  
**Dr Emily Davies**

Great Western Hospitals NHS Foundation Trust  
**Dr Lindsay Whittam**

Guys & St Thomas NHS Foundation Trust  
**Prof Jonathan Barker and Mr John Gregory**

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Harrogate and District NHS Foundation Trust  
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Medway NHS Foundation Trust  
**Dr Eoin Storan**

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Newcastle upon Tyne Hospitals  
NHS Foundation Trust  
**Prof Nick Reynolds**

Newcastle upon Tyne Hospitals  
NHS Foundation Trust  
**Prof Nick Reynolds**

NHS Ayrshire & Arran  
**Mrs Alison Love**

NHS Borders  
**Mrs Alison Love**

NHS Dumfries and Galloway  
**Dr Lindsey Yeo**

NHS Fife (Dunfermline Queen Margaret)  
**Dr Sally McCormack**

NHS Fife (Victoria Hospital Kirkcaldy)  
**Dr Ann Sergeant**

NHS Forth Valley  
**Dr Fiona Craig**

NHS Grampian  
**Dr Sanjay Rajpara**

NHS Greater Glasgow and Clyde  
**Dr Gabrielle Becher**

NHS Highland  
**Dr Siddharth Basetti**

NHS Lanarkshire  
**Dr Freida Shaffrali**

NHS Lothian  
**Dr David Mckay**

NHS Tayside  
**Dr Robert Hearn**

Norfolk and Norwich University Hospitals  
NHS Foundation Trust  
**Dr Nick Levell**

North and North East Lincolnshire Dermatology  
(Virgin Care)  
**Dr Prakash Gowda**

North Cumbria Integrated Care  
NHS Foundation Trust  
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