



# Dermatology



Many of our PIs are highly experienced in conducting trials and treating patients with a range of dermatological conditions



We have conducted **20+** studies in dermatology over the past five years



We are experienced in conducting and executing complex and specialised dermatology studies

## Driving Clinical Excellence in Dermatological Studies



We conduct dermatology research in our Early Phase Unit, located in Manchester, and in our multiple late-phase sites across the UK, including Merseyside, Yorkshire, Teesside, Lancashire and South Staffordshire. We can also run trials anywhere across the globe via our robust site network.



We have conducted studies with small molecules, microbiomes and biologics. We have administered IMPs via a range of routes including oral, topical, IV and sub-cutaneous routes.



Study designs range from niche, first-in-human, proof-of-concept, single-centre studies to large, Phase 3, pre-registration and multi-centre studies. We have designed, developed and executed umbrella, adaptive, and dose escalation studies for biotech and pharmaceutical companies.



We work with a range of sponsors, from small start-up biotechs to leading pharmaceutical companies.



Our team of expert statisticians and analysts offers high-quality data output via purpose-built software, giving you the data and reporting capabilities you need to support your products.

## Dermatology Rating Scales

### General

Body Surface Area (BSA)  
 Body Map Recording  
 Fitzpatrick Skin Assessment

### Atopic Dermatitis

Eczema Area & Severity Index (EASI)  
 SCORing Atopic Dermatitis (SCORAD)  
 Investigator's Global Assessment (IGA)

### Psoriasis

Psoriasis Area & Severity Index (PASI)  
 Static Physicians Global Assessment (sPGA)  
 Scalp-specific Physician's Global Assessment (ss-PGA)  
 Physician's Global Assessment – Fingernails (PGA-F)

**We have expertise in conducting a variety of rating scales for dermatology studies**

- ▶ **Sponsor training is coupled with our own in-house training to ensure optimum results**
- ▶ **Our highly experienced dermatological raters conduct all consistency checks**

## Patient-Reported Outcomes

Peak Pruritis NRS (Peak Pruritis Severity & Frequency)  
 Worst Itch Numeric Rating Scale (WI-NRS)  
 Current Itch NRS  
 Skin Pain NRS  
 Patient Global Assessment (PGA)  
 Patient-Oriented Eczema-Measure (POEM)  
 PROMIS® Itch Instruments  
 Dermatology Quality of Life Index (DLQI)  
 European Quality of Life Five-Dimension Questionnaire (EQ-5D)  
 Work Limitations Questionnaire (WLQ)  
 Psoriasis Symptoms and Signs Diary (PSSD)  
 Hospital Anxiety & Depression Scale (HADS)  
 Insomnia Severity Index (ISI)



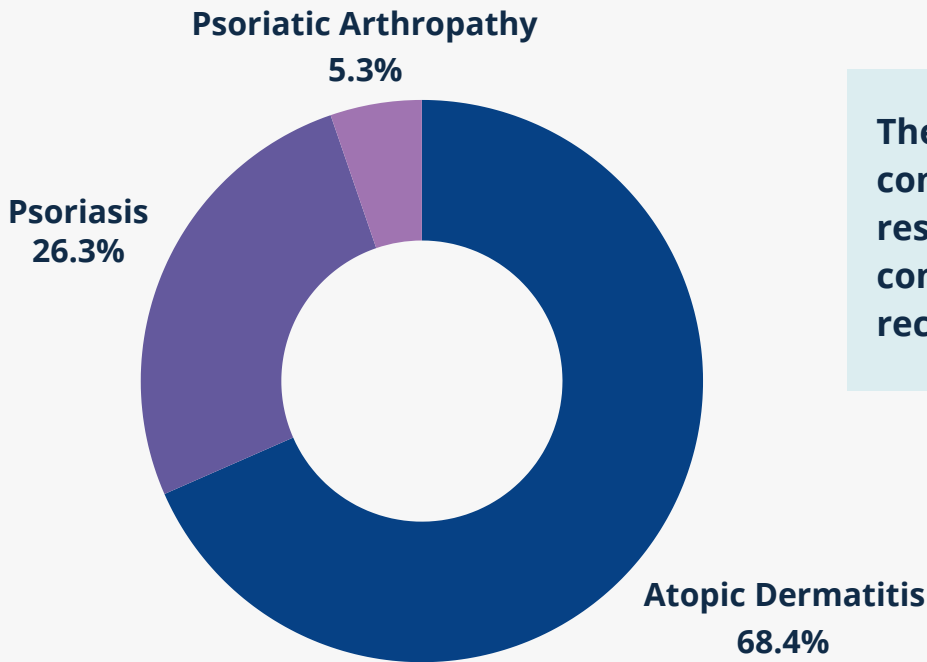
## Skin Punch Biopsy

Our medical team is highly experienced in performing skin biopsies, which are required for exploratory endpoints and biomarker/PD analysis in many dermatology studies. We can perform biopsies in-house, and offer pre- and post-procedure care to trial subjects. Our clinical and laboratory teams are skilled in processing and analysing the biopsy samples for complex biomarkers.





# Dermatology Studies



The dermatology studies we conduct deliver outstanding results with our late-phase sites consistently outperforming other recruiting sites.

## Case Study

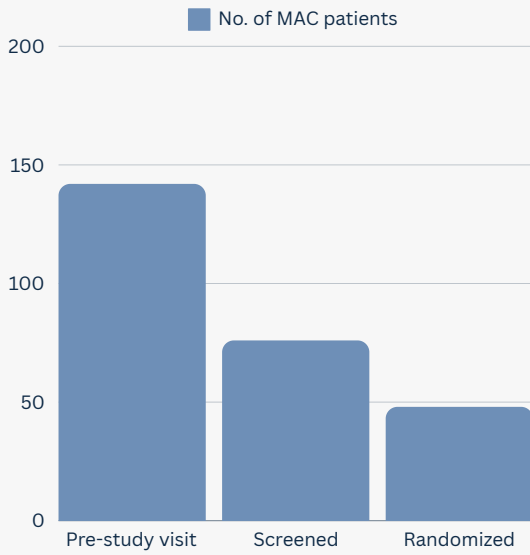
### Integrated study for a new topical treatment for eczema



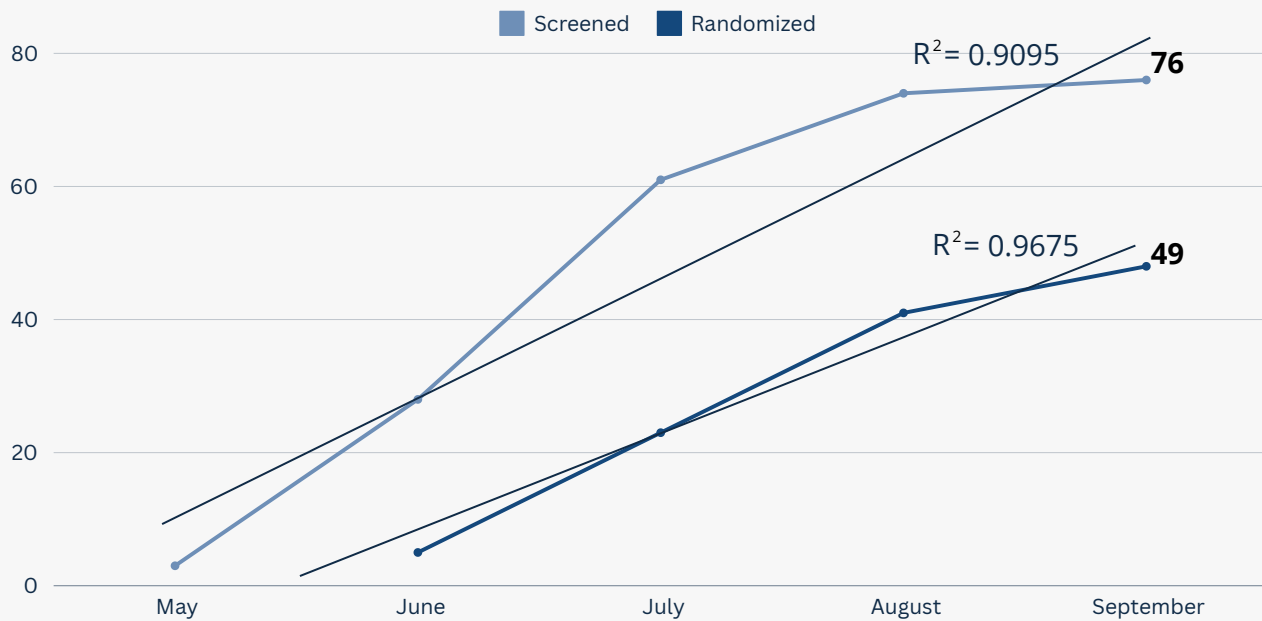
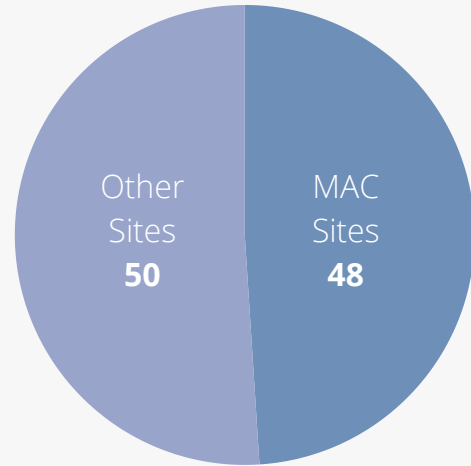
- Cohort of 12 inpatient healthy volunteers to assess safety and tolerability data, followed by a cohort of inpatient eczema patients
- Expansion to a cohort of 30 outpatient eczema patients to obtain longer-term efficacy data
- Outcome: the study moved a compound from the start of Phase 1 to the end of Phase 2 under a single protocol, and was completed within 6 months, providing the client with enough information to sell the asset for further development.

## Case Study

### Atopic Dermatitis Study - Phase II



Total number of enrolled patients by site



## Summary

- 24 sites initiated (including 4 MAC sites)
- MAC randomized 49% of total patients
- MAC had the three highest-recruiting sites
- Linear trend in recruitment with a strong Coefficient of Determination ( $R^2$ )
- 16 sites recruited patients, including MAC's 4 sites
- 33% of initiated sites did not recruit any patients

## Our dermatology experts



**Dr Aliya Asher**  
Chief Medical Officer

Dr Aliya Asher has provided clinical oversight and acted as Chief Investigator, PI, or Sub-I on several dermatology trials conducted at MAC, including First-in-Human (FIH) through later phases, for treatments for atopic dermatitis, psoriasis, and psoriatic arthritis.

Dr Asher has also co-authored a paper that was presented to the European Academy of Allergy and Clinical Immunology: A phase-2a, proof-of-concept clinical trial to evaluate XXX-XXXXXX, a potent oral histamine H4-receptor antagonist for the treatment of moderate-to-severe atopic dermatitis (AD) in adults.



**Dr Alex Thompson**  
Clinical Research  
Physician

Dr Alex Thompson is a highly experienced Senior Clinical Research Physician in dermatology at MAC. Dr Thomson has spent many years as both PI and Sub-I in dermatological studies, covering therapy areas such as Atopic Dermatitis, Psoriasis, Fungal Nail Infection, MRSA, and Leg Ulcers.

Dr Thomson has conducted over 300 studies as a PI, and has trained skin assessors to identify various skin conditions to ensure rating consistency amongst his team. He has administered many dermatology assessment scales, including EASI, PASI, BSA, PGA, IGA/CGIC, C-SSRS, HAD-A&D, EQ-5D, and SF-36, as well as other sleep, quality-of-life, and itch assessments.

# MAC Clinical Research

- ✓ Over 30 years' experience in conducting clinical studies
- ✓ Full-service CRO with global reach
- ✓ 10 fully-owned research facilities in the UK
- ✓ Experts in healthy volunteer and patient recruitment



## 5-year summary

**120+**

SPONSORS

**250+**

STUDIES

**50+**

INDICATIONS

**20+**

FIH STUDIES

## Our Services



### CLINICAL RESEARCH SERVICES

**Project Management**

**Clinical Operations**

Site Monitoring  
Site Management  
Trial Feasibility

**Pharmacovigilance**

**Regulatory Affairs**

**Biometrics**

EDC  
Data Management  
SAS Programming  
Biostatistics  
Medical Writing

**Vendor Management**

**Randomization and Trial Supply Management**

**Digital Solutions**

Electronic Patient-Reported Outcomes (ePRO)  
eConsent

**Medical Monitoring**



### SITE & PATIENT SERVICES

**Participant Recruitment**

**Participant Retention**

**Global Investigator Sites**

**Network of Fully-Owned Investigator Sites**

Sleep Laboratory  
Early Phase Unit  
Psychedelic Testing Suites  
Phase I - IV Research Facilities  
Memory Assessment Research Centre



### SCIENTIFIC SOLUTIONS

**Human Models of Disease**

**Scientific and Endpoint Assessments**

Cardiovascular Assessments  
Cognitive and Neuropsychological Assessments  
Dermatology Assessments  
Imaging Assessments  
Neurophysiology Assessments  
Pain Assessments  
Other Assessments  
Rare diseases

**Sleep Assessments**

**Psychedelics**

**Training**



### PHARMACEUTICAL SERVICES

**GMP Manufacturing**

**In-House Pharmacy**

**Global Clinical Supplies**

**QP Release**

**IMP Management & Distribution**

**Controlled Drug Services**

**Laboratory Services**

Clinical Pathology  
Bioanalytical Services



### STRATEGIC CONSULTANCY

**Therapeutic Area Expertise & Study Development**

**Scientific Solutions & Pharmacodynamics**

**Clinical Science & Development**

**Medical Strategy, Input & Expertise**

**Statistical Analysis, Planning & Advice**

**Medical Writing**

**Laboratory Study Design, Methods & Conduct**

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