An Immuno-Dermatological disease registry to understand the burden of Atopic dermatitis (AD), Alopecia areata (AA), and Vitiligo in Indian Patients

First published: 17/04/2023 Last updated: 21/02/2025





## Administrative details

**Study description** 

EU PAS number	
EUPAS48566	
Study ID	
106116	
DARWIN EU® study	
No	
Study countries	
☐ India	

A prospective observational multi-center study in India to evaluate the epidemiological burden of mild, moderate and severe atopic dermatitis, vitiligo and alopecia areata.

#### **Study status**

Ongoing

## Research institutions and networks

### **Institutions**

### Pfizer

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Institution

- DY Patil Hospital
- Father Muller Medical College Hospital
- Wizderm Specialty Skin and Hair Clinic
- Vibrance Skin Clinic
- Indushree Skin Clinic
- Lokmanya Tilak Municipal General Hospital and Lokmanya Tilak Municipal Medical College

- Bharati Vidyapeeth (deemed to be University) Medical College Hospital & Research Centre
- KPC Medical College and Hospital
- Ayana Clinic
- B. J. Medical College & Civil Hospital
- Venkateshwar Hospital
- Dermaworld Skin Clinic
- Dr. D.Y.Patil Medical College, Hospital and Research
- Maharishi Markandeshwar Institute of Medical sciences and Research
- Indus International Hospital

### **Networks**

Insignia

Contact details

Study institution contact

### Komal Vinodkumar Gaur komal.gaur@pfizer.com

Study contact

komal.gaur@pfizer.com

### Primary lead investigator

Hala Sayed

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Planned: 02/05/2022

Actual: 28/06/2022

#### Study start date

Planned: 29/09/2023

Actual: 28/08/2023

#### Date of interim report, if expected

Planned: 31/01/2026

#### **Date of final study report**

Planned: 30/12/2026

# Sources of funding

• Pharmaceutical company and other private sector

## More details on funding

Pfizer

# Study protocol

B7451103 Non-Interventional Study Protocol Version 1.0\_ 30 September 2022\_Redacted.pdf (3.71 MB)

B7451103\_NIS Protocol v3.0\_Amendment 2 Clean Copy 23DEC2024 Redacted.pdf (4.07 MB)

# Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

# Methodological aspects

Study type

Study type list

**Study topic:** 

Disease /health condition

#### Study type:

Non-interventional study

#### Scope of the study:

Disease epidemiology

### Main study objective:

The objective of this study is to evaluate the epidemiological burden of mild, moderate and severe atopic dermatitis, vitiligo, and alopecia areata across enrolled dermatology centers.

# Study Design

### Non-interventional study design

Cohort

Cross-sectional

Other

### Non-interventional study design, other

Prospective longitudinal study

# Study drug and medical condition

#### Medical condition to be studied

Dermatitis atopic

Alopecia areata

Vitiligo

# Population studied

#### Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)</li>
- Adults (18 to < 46 years)</li>
- Adults (46 to < 65 years)

### **Estimated number of subjects**

3000

# Study design details

#### **Outcomes**

To evaluate the epidemiological burden of mild, moderate and severe atopic dermatitis, vitiligo and alopecia areata in patients across dermatology centers in India.

Explain the current diagnostic criteria and grading modalities for AD, vitiligo and AA, to understand the burden of disease with a demographic overview Better understand the treatment for the diseases: topical, advanced therapies, surgical interventions and cosmetic procedures, the Unmet needs in diagnosis and management of dermatological disorders. Focus on patients' perspectives on benefits.

#### Data analysis plan

Descriptive statistics will be presented to describe patient characteristics.

Categorical covariates will be described by frequency distribution while continuous covariates expressed in terms of their mean and standard deviation or median and interquartile range (IQR) as appropriate.

The bivariate analysis will be conducted to determine if there is any association between the outcome and the exposure (the covariates).

Unadjusted comparisons between groups of covariates and outcomes will be evaluated using appropriate tests: Pearson's chi-square test will used for dichotomous categorical variables, t-test will be used for continuous variables, and the Mann-Whitney U test for non-parametric variables, p-values will be generated and 5% level of significance will be considered.

In case of multiple testing or stepdown procedure either Tukey HSD or Bonferroni adjustment to p-value will be applied.

### **Documents**

#### Study, other information

B7451103 Non Interventional Study Protocol Abstract V2.0\_19 April 2023\_Redacted.pdf (719.94 KB)
B7451103 Protocol Abstract 30 September 2022\_Redacted.pdf (1.89 MB)
B7451103\_NIS Protocol Abstract V3.0\_Clean Copy\_23DEC2024\_Redacted.pdf (732.41 KB)

## Data management

### **ENCePP Seal**

The use of the ENCePP Seal has been discontinued since February 2025.

The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

Other	(types)				
Data sources	(types), othe	r			
Prospective pa	ient-based dat	a collectio	n		
Use of a (	Common	Data N	Model (	CDM)	
CDM mapping					
No					
Data qua	ity spacit	fication	2.5		
Data qua	ity specii	icatioi	15		
Check confor		icatioi	15		
•		icatioi	15		
Check confor	nance	icatioi	15		
Check confor	nance	icatioi	15		
Check conford Unknown Check comple	nance teness	icatioi	15		

# Data characterisation

### **Data characterisation conducted**

No