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

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Name and Affiliation:

Redacted

Rationale and Background:

Nationwide systematic studies identifying the disease burden, epidemiology, and challenges and unmet needs in the diagnosis and management of AD, vitiligo, and AA in India are lacking.

To have an Indian Immuno-Dermatological registry amongst Indian patients, suffering from AD, vitiligo, and AA to:

- Evaluate the epidemiological burden of AD, vitiligo, and AA.
- Current diagnostic modalities.
- Burden of diseases – pediatric population, adult patients, mild, moderate, or severe.
- Treatment – topical therapies, advanced therapies across the spectrum of the disease.
- Unmet needs in diagnosis and management of diseases – Need for newer alternative therapies for patient's refractory to current therapeutic alternatives.

Atopic dermatitis (AD) is a chronic, pruritic inflammatory skin disease that occurs most frequently in children but also affects many adults. It has a relapsing course and is often associated with elevated serum IgE levels and a personal or family history of allergic rhinitis and asthma. AD is one of the most common skin diseases which affects up to 20% of children and 1%–3% of adults in most countries of the world. It is often the first step in the development of other atopic diseases such as rhinitis and/or asthma. There is, however, no documentation of an atopic march from India.[1]The exact prevalence of, vitiligo and atopic dermatitis (AD) in India is not known and we rely on Western data.[2] Vitiligo is an acquired, idiopathic, and common depigmentation disorder. The values of various epidemiologic parameters of vitiligo are often doubtful due to the methodological weaknesses of the studies.[3] Alopecia areata (AA) is a common form of non-scarring alopecia involving the scalp and/or body, characterized by hair loss without any clinical inflammatory signs. It is one of the most common forms of hair loss seen by dermatologists and accounts for 25% of all the alopecia cases.[4] The information on prevalence would be useful for planning strategies to manage these diseases.[2]

This non-interventional study is designated as a PASS and is conducted voluntarily by Pfizer.

Research Question and Objective:

Primary objective

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

Secondary objectives

- To elucidate the Current diagnostic criteria and grading modalities for AD, vitiligo, and AA in India.

- Burden of disease with a demographic overview of AD, vitiligo, and AA – with factors like Age (adult/adolescent/Pediatric), Gender (Male/female), Severity, region of body affected, Comorbidities, relevant personal history.

- Treatment for AD, vitiligo, and AA – topical therapies, advanced therapies across the spectrum of the diseases, surgical interventions and laser or other cosmetic procedures across the disease severity spectrum.

- Unmet needs in diagnosis (sequence of treatment and adverse events on therapy) and management of dermatological disorders Need for newer alternative therapies for patient's refractory to current therapeutic alternatives.

- Focus on patients' perspectives on benefits, quality of life and on the sequence of treatments.

Study Design/Setting:

A prospective, observational, longitudinal study (Immuno-Dermatological disease registry) conducted in multiple centers across India.

There is no study-related intervention. Enrolled patients are observed for the entire study period for a minimum of 3 follow-ups. Post baseline visit, follow-up visits take place at intervals at the investigator's discretion.

At each follow-up visit, the investigator documents the clinical examination findings as per the CRF, the prescribed therapy including the rationale for the prescription, as well as reasons for a change or continuation of therapy and possible adverse drug reactions (ADR) if any.

The patient questionnaire for follow-up visits is similar to the questionnaire for the baseline visit.

All assessments described in this protocol are performed as part of normal clinical practice or standard practice guidelines for the patient population and healthcare provider specialty in the countries where this non-interventional study is being conducted.

Population:

Adults and children, aged between 2 and 64 years old, who have been clinically diagnosed with AD, vitiligo, and AA will be included in the study.

Variables:

To note the age at diagnosis, the severity of disease, treatment initiation, treatment switch to advanced therapies, time to remission, time to relapse, patients with refractory disease, diagnosis at admission, patient demographics, underlying co-morbidities, treatment history, history of atopy, concomitant medications, clinical characteristics, clinical outcomes, use of topical therapy, the duration for moisturizers, quality of life parameters.

For Atopic Dermatitis[5]

Clinician Reported Outcomes

- Age of Onset and progress of the disease;
- Choice of therapy as I/II line agents;
- Use of phototherapy;
- Treatment of relapse (Topical/Systemic);
- Maintenance drugs (Topical/Systemic);
- Use of phototherapy;
- Other medications: antibiotics/antihistaminic;
- Use of moisturizers;
- Hospitalizations;
- QoL: loss of daily work/school days;
- Body Surface Area (BSA) Involvement;
- Eczema Area and Severity Index (EASI);
- SCORing Atopic Dermatitis (SCORAD);
- Validated Investigator Global Assessment scale for Atopic Dermatitis (vIGA-AD);
- Nail changes due to atopic dermatitis (graduated Visual Analogue Scale);
- Dermatology life quality index (DLQI);

- Children's dermatology life quality index (CDLQI);
- Infants' dermatitis quality of life index (IDQOL);
- Patient-Oriented Eczema Measure (POEM);
- Dermatitis Family Impact Questionnaire.

Patient Reported Outcomes

- Patient assessments of disease control and severity (Whichever scale is applied by investigator).

For Alopecia Areata[6]

Alopecia areata: alopecia partialis (patchy loss of the scalp hair), alopecia totalis (total loss of all scalp hair), and alopecia universalis (complete loss of all hair everywhere on the body).

- Diagnosed with alopecia areata (Scalp, Skin over the body and nails by a dermatologist).
- Diagnostic parameters used.
- Associated diseases.
- Treatment.
- Nail changes.
- Alopecia Areata symptom impact scale (AASIS).
- Severity of Alopecia Tool (SALT).
- Dermatology life quality index (DLQI).

For Vitiligo[7]

- Natural history.
- Risk factors.
- Current medications.

Past vitiligo treatments (dose, duration, response, adverse effects, satisfaction).

- Patient-reported body surface involvement.
- Use of vitiligo scales.

- Vitiligo Disease Activity Score (VIDA) %.
- Koebner score.
- VITI QoL.
- Dermatology life quality index (DLQI).

Data Sources:

According to the inclusion and exclusion criteria specified in the protocol, Investigators are to recruit patients for the specified conditions, AD, vitiligo and AA.

Primary data collected by the investigator himself through patient enrollment as per the protocol inclusion & exclusion criteria, observation & questionnaire during baseline & follow -up visits of the patient to the Investigator as per the CRFs.

The data is primarily collected electronically in EDC or in paper CRF's.

It is the investigator's responsibility to ensure that the study is conducted in compliance with all legal requirements and that the data are correctly recorded in the CRFs.

All data generated in the course of this study (including concomitant diseases, results of examinations and adverse events) must be recorded in the CRFs by appropriately authorized persons.

Study Size:

The total study duration is estimated to be 3 years. The enrollment of all participants would be completed by 18 months with a follow up visit after a minimum of 18 months. A total of 3000 patients will be recruited and the sample distribution will be as follows:

- *1500 AD patients – The enrollment would proceed in a phased manner with evaluation on enrollment every 6 months.*
- *750 vitiligo patients.*
- *750 AA patients.*

Data Analysis:

Detailed methodology for summary and statistical analyses of data collected in this study will be documented in a statistical analysis plan (SAP), which will be dated, filed and maintained by the sponsor. The SAP may modify the plans outlined in the protocol; any major modifications of primary endpoint definitions or their analyses would be reflected in a protocol amendment.

Milestones:

Milestones	**Planned Date**
Completion of feasibility assessment	31 Aug 2022
Start of Data Collection	31 Oct 2022
End of Data Collection	05 Oct 2025
Registration in the EU PAS Register	15 Oct 2022
Final Study Report	21 Apr 2026

1. REFERENCES

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