

# Design and Rationale of ARMADA-AD Disease Registry: An International, Prospective, Observational Registry to Characterize Unmet Needs and Evaluate Real-World Effectiveness and Safety of Systemic Therapies in Adults and Adolescents with Atopic Dermatitis

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## Key Conclusion

Data collected from the ARMADA-AD registry will address existing gaps and serve as a valuable resource to further our understanding of unmet needs and burden of AD, and real-world safety and effectiveness of systemic therapies, compared to other registries

## Introduction

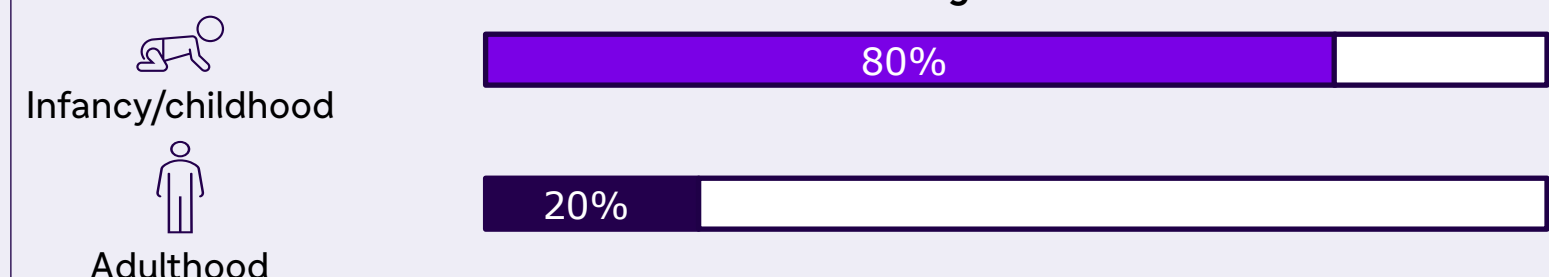
Atopic dermatitis (AD) causes significant burden to patients and negatively impacts quality of life.

AD is a heterogenous chronic inflammatory disease affecting ~230 million people<sup>1,2</sup>

Despite recent advances, significant **unmet needs** remain among patients with AD<sup>2-4</sup>:

- Long-term safety
- Burden of current treatments
- Disease relapse
- Limited therapies targeting heterogenous inflammation
- Lack of remission in ongoing therapies

Cases observed during<sup>2</sup>



## Objective

To present the design of **ARMADA-AD disease registry** that aims to collect real-world data:

- To characterize the existing unmet needs across the spectrum of disease in adolescent and adult patients with atopic dermatitis
- To enhance the understanding of the patient journey and healthcare professionals' clinical decision-making, and
- To evaluate the long-term safety and effectiveness of products post-approval in real-world

## Methods

**ARMADA-AD Disease Registry: Study Outline**  
Prospective Real-World Registry on Adolescent and Adult Atopic Dermatitis Patients

### Key Inclusion Criteria

- Age ≥12 years at the time of screening with confirmed diagnosis of AD
- Currently initiating or switching a systemic therapy for AD (including, but not limited to biologics, oral JAKi, UV therapy, and immunosuppressive/immunomodulatory therapies)

### Key Exclusion Criteria

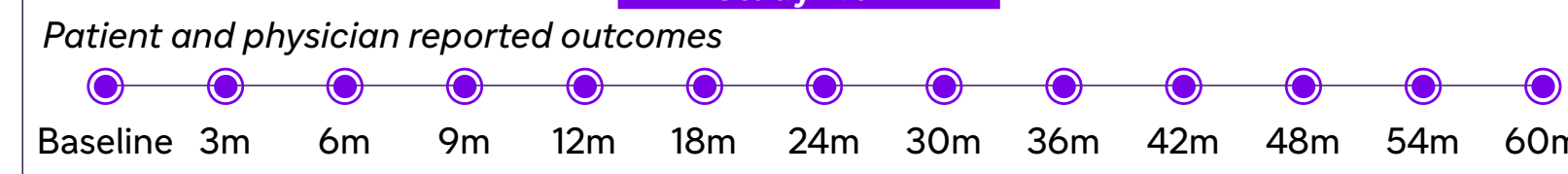
- Concurrent participation in an interventional clinical trial that administers an investigational drug that modifies patient care. Insufficient understanding of the study by the patient and/or parent/guardian

### Study Design

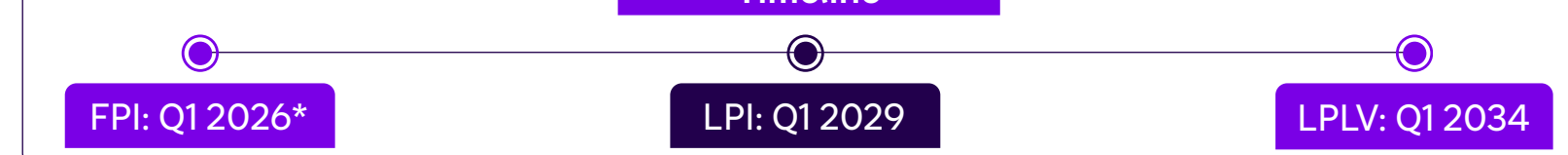
**Study type:** International, multi-center, longitudinal, prospective, non-interventional, observational, real-world study of adolescent and adult patients with AD

**Population:** ~1000 **~142 sites from:** US, Germany, France, China, Japan, Italy, Spain, Canada, UAE, Saudi Arabia

### Study Flow



### Timeline



\*Potential to move it to H2 2025.

## Outcome Measures

**Objectives** | **Endpoints**

### Primary

- To observe and describe systemic therapy for AD utilization patterns over the follow-up period
- To describe effectiveness while being treated with systemic therapy for AD measured using ClinRO and PROs over follow-up
- Systemic therapy utilization for AD over the follow-up period, up to 60 months including treatment duration and sequence, reason for initiating treatment, treatment interruption, discontinuation, switching and augmentation
- Change from index treatment date while being treated with systemic therapy for AD for the following over the follow-up period, up to 60 months:
  - **ClinROs:** EASI (severity) BSA (skin affected, remission), vIGA-AD (severity, remission)
  - **PROs:** ADCT (AD control), PGI-S (severity), PP-NRS (itch severity, remission), SP-NRS (skin pain), SD-NRS (sleep disturbance)

### Secondary

- To describe patient demographic and clinical characteristics
- To describe quality of life, depression and anxiety, productivity, and treatment satisfaction while being treated with systemic therapy for AD using PROs
- To describe healthcare resource utilization over the follow-up period
- To evaluate time course of AD, selected comorbid atopic and non-atopic conditions at baseline and over follow-up
- To describe concomitant medications, use at baseline and over follow-up
- Patient demographics and clinical characteristics (demographics, employment status, history of AD and selected comorbidities)
- Change from index treatment date while being treated with systemic therapy for AD for the following PROs over the follow-up period, up to 60 months: DLQI, Children's DLQI, HADS, WPAI-AD, TSQM-9
- Healthcare resource utilization (visit with type of attending HCP and reason for visit, hospitalizations due to AD) over the follow-up period, up to 60 months
- Prevalence and incidence of selected atopic and non-atopic comorbidities at baseline and over the follow-up period, up to 60 months
- Concomitant medication use and changes (including reasons for change)

### References

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### Abbreviations

AD, Atopic Dermatitis; ADCT, Atopic Dermatitis Control Tool; BSA, Body Surface Area; ClinRO, Clinician Reported Outcome; DLQI, Dermatology Life Quality Index; EASI, Eczema Skin and Severity Index; FPI, First Patient In; H2, Second half of the year; HADS, Hospital Anxiety and Depression Scale; HCP, Health Care Professional; JAKi, Janus Kinase Inhibitor; LPI, Last Patient In; LPLV, Last Patient Last Visit; m, months; PGI-S, Patient Global Impression of Severity; PP-NRS, Peak Pruritus Numeric Rating Scale; PRO, Patient Reported Outcome; Q1, Quarter 1; SD-NRS, Sleep Disturbance Numeric Rating Scale; TSQM, Treatment Satisfaction Questionnaire for Medication; UAE, United Arab Emirates; US, United States of America; UV, UltraViolet; WPAI, Work Productivity and Activity Impairment.

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