Systemic Treatments Outcomes for **Moderate-to-Severe Atopic Dermatitis** in **Children** Under 12 Years Old: 5-Year Results of **PEDISTAD** Registry Study

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Learning objective

To report the long-term effects of systemic therapies on clinician-reported outcomes in children aged <12 years with moderate-to-severe AD enrolled in the PEDISTAD study

Takeaway message

Patients treated with dupilumab had a numerically greater improvement in clinician-reported AD signs and lower discontinuation rates compared with patients treated with methotrexate or cyclosporine

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Background

Dupilumab treatment has been shown to significantly **improve AD signs and symptoms** in children aged <12 years enrolled in the PEDISTAD study[1]

Real-world studies offer valuable insights into the long-term effect of systemic therapies in infants and children, helping the **sustained management of AD**

1.Paller AS et al, J Am Acad Dermatol, 2025.
AD, atopic dermatitis.

Objective

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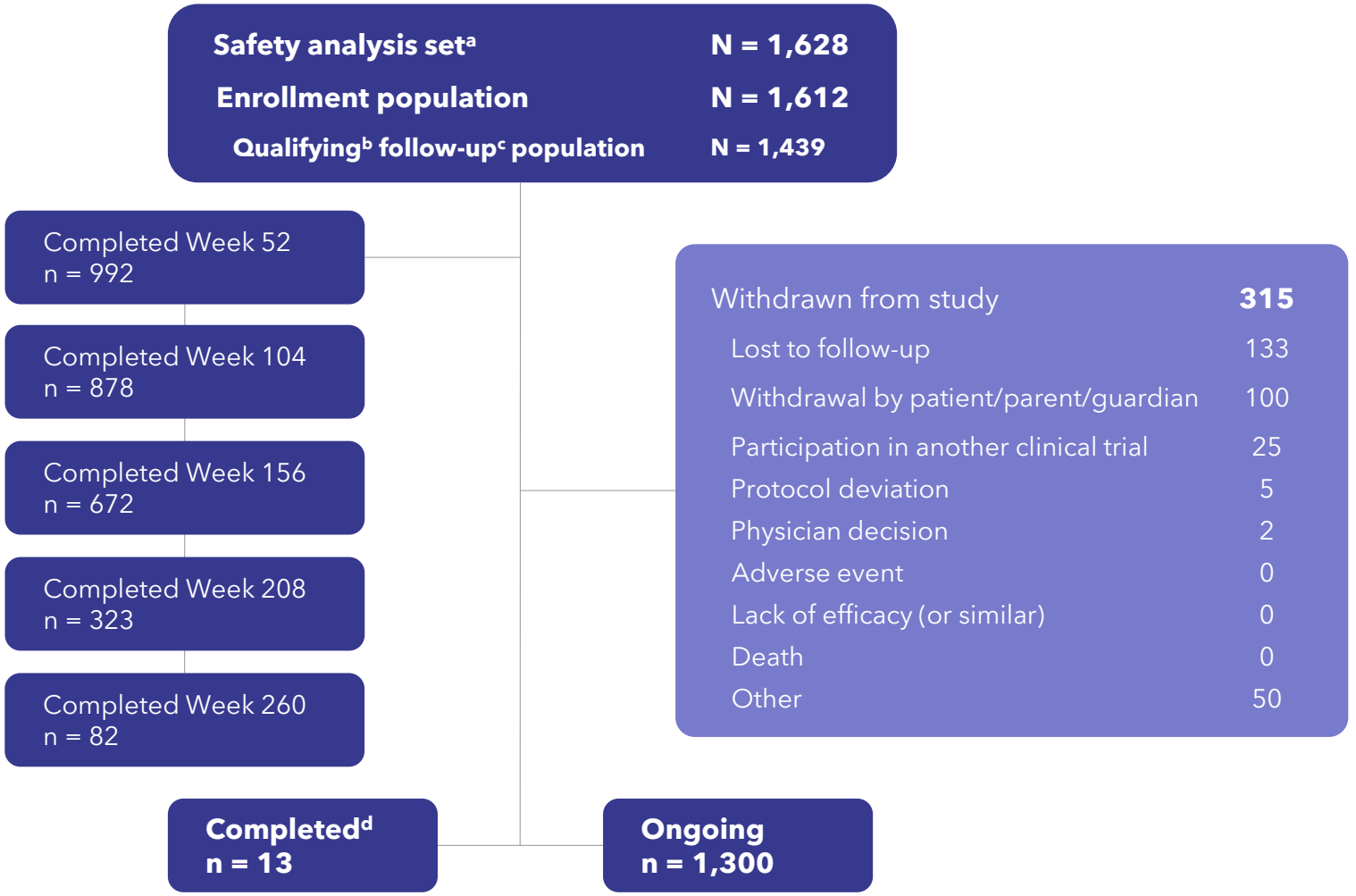
To report the **long-term effects** of **systemic therapies** on clinician-reported outcomes in **children aged <12 years** with **moderate-to-severe AD** enrolled in the 10-year PEDISTAD observational study

Methods

- **PEDISTAD** (NCT03687359) is an ongoing, international, observational 10-year registry study in **children** with **moderate-to-severe AD, aged <12 years** at enrollment, who were receiving/were candidates for systemic treatment
- This 5-year interim analysis of PEDISTAD reports **mean EASI score** and the **percentage affected BSA** for patients receiving **dupilumab, methotrexate,** or **cyclosporine**
- The **number of AEs** and **discontinuations**[a] were also evaluated
- Data are presented as observed

[a]When the patient discontinued study for any reason.
AE, adverse event; BSA, body surface area; EASI, Eczema Area and Severity Index.

Patient disposition



[a]Any patient who completed the enrollment visit (Visit 1). Same as qualifying enrollment population. [b]Qualifying patients who meet all the study's eligibility criteria.[c]Follow-up population: includes all enrolled patients who completed at least one follow-up visit after Visit 1. [d]patients completing 5 years of follow-up.

Baseline demographics

Results

	Dupilumab n = 360	Methotrexate n = 152	Cyclosporine n = 151	Total enrolled population N = 1,612
Age, mean (SD), years	6.5 (2.84)	6.9 (2.84)	7.0 (2.66)	5.4 (3.18)
<2 years, n (%)	1.3 (0.35)	1.2 (0.55)	0.8 (0.07)	238 (14.8)
2 to <6 years, n (%)	3.8 (1.04)	4.0 (0.92)	3.9 (0.93)	645 (40.0)
6 to <12 years, n (%)	8.5 (1.75)	8.6 (1.87)	8.5 (1.64)	729 (45.2)
Male, n (%)	200 (55.6)	88 (57.9)	73 (48.3)	852 (53.1)
Race, n (%)				
American Indian or Alaska Native	6 (1.7)	5 (3.5)	3 (2.1)	20 (1.3)
Asian	104 (30.2)	18 (12.8)	33 (23.1)	434 (28.0)
Black or African American	35 (10.2)	15 (10.6)	14 (9.8)	152 (9.8)
White	180 (52.3)	90 (63.8)	80 (55.9)	857 (55.4)
Other	19 (5.5)	13 (9.2)	13 (9.1)	44 (2.8)
Hispanic/Latino, n (%)	59 (19.4)	64 (47.8)	45 (37.2)	437 (31.7)

Mean (SD) treatment exposure[a] was 21.3 (17.4) months for dupilumab, 20.2 (16.9) months for methotrexate, and 13.6 (13.2) months for cyclosporine

[a]Exposed duration (months) is defined for AD only and for time periods with no changes in dose, from baseline until end of follow-up, inclusive of both days; it will be calculated as sum of treatment periods (end date – start date + 1)/30.4 per patient. SD, standard deviation.

Disease characteristics

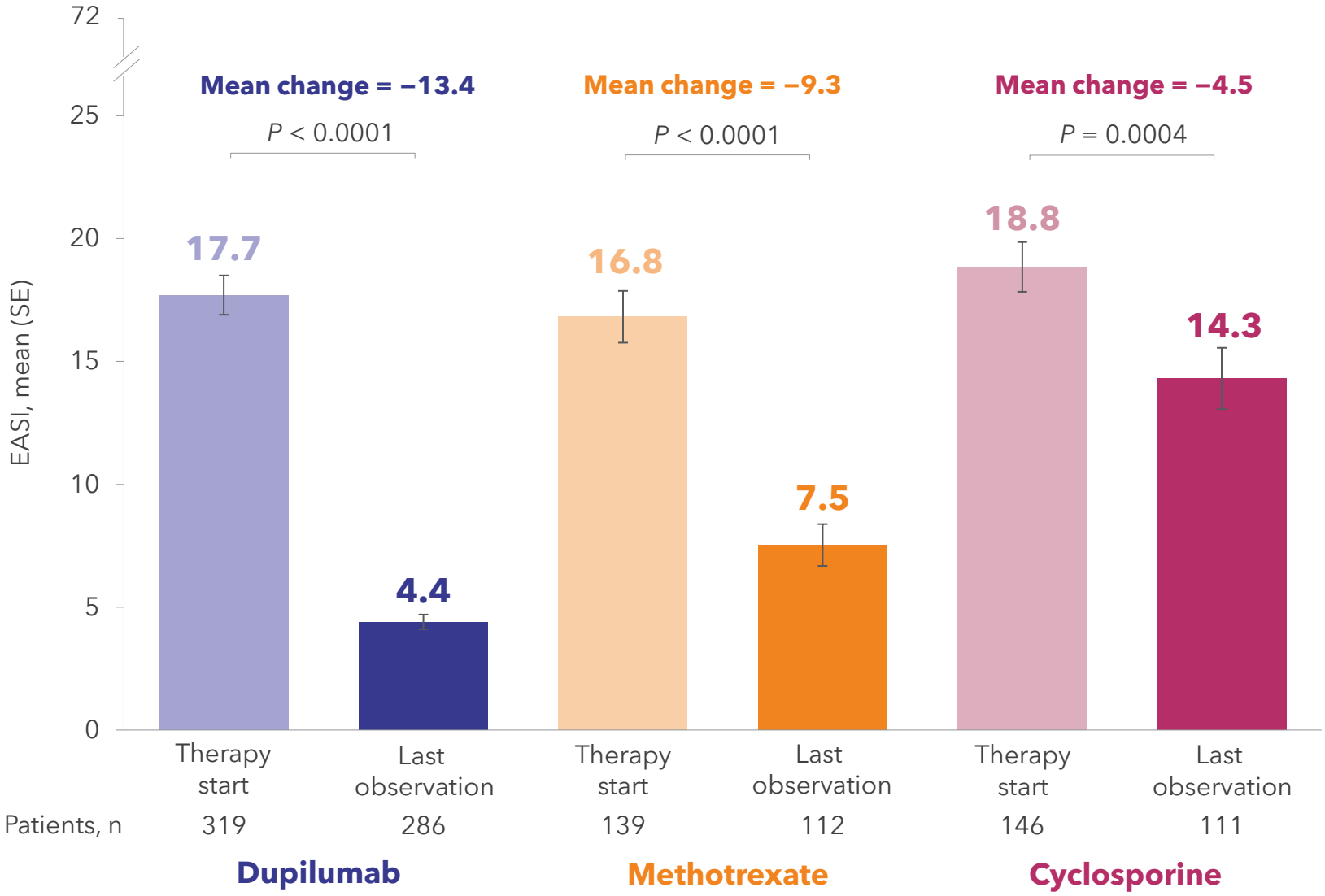
Results

	Dupilumab n = 360	Methotrexate n = 152	Cyclosporine n = 151	Total N = 1,612
Age at AD onset, mean (SD), years	1.2 (1.71)	1.5 (1.89)	1.4 (1.82)	1.4 (1.90)
Any concomitant AD comorbidity, n (%)[a]	266 (73.9)	108 (71.1)	113 (74.8)	949 (58.9)
ADD/ADHD	21 (5.8)	11 (7.2)	5 (3.3)	22 (1.4)/43 (2.7)
Allergic conjunctivitis	58 (16.1)	21 (13.8)	25 (16.6)	175 (10.9)
Allergic rhinitis	145 (40.3)	61 (40.1)	68 (45.0)	518 (32.1)
Anxiety	27 (7.5)	13 (8.6)	10 (6.6)	58 (3.6)
Asthma	122 (33.9)	59 (38.8)	48 (31.8)	349 (21.7)
Eosinophilic esophagitis	7 (1.9)	4 (2.6)	-	15 (0.9)
Food allergy	176 (48.9)	68 (44.7)	65 (43.0)	555 (34.4)
Nasal polyposis	3 (0.8)	2 (1.3)	1 (0.7)	9 (0.6)
Clinical-reported outcomes, mean (SD)[b]				
EASI, range: 0–72	17.2 (13.1)	17.0 (12.5)	18.3 (11.5)	14.1 (11.0)
BSA, range: 0–100	35.3 (22.8)	35.1 (21.8)	39.2 (22.3)	32.3 (21.2)

Percentages were calculated using the number of non-missing observations (n) as the denominator; [a]Any conditions ongoing at or started on or after study entry (Visit 1, Month 0). Patients reporting the same MeDRA PT multiple times were counted only once for the same PT; [b]Higher values indicate a worse outcome for each of the clinical measures.
ADD, attention deficit disorder; ADHD, attention deficit hyperactivity disorder; MedDRA, Medical Dictionary for Regulatory Activities; PT, MedDRA Preferred Term.

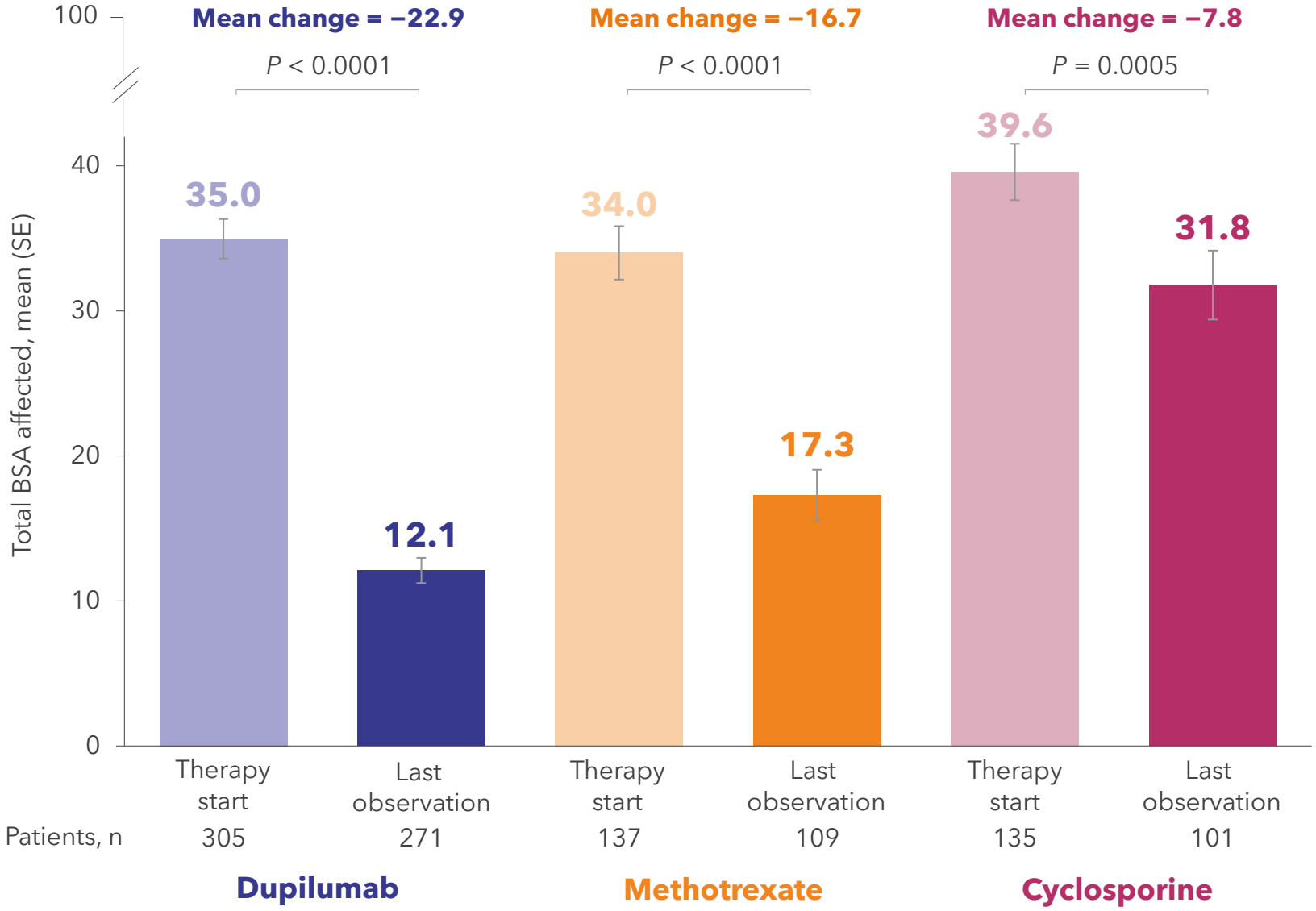
- Pediatric p**atients receiving dupilumab had** numerically **greater improvements in EASI vs patients receiving methotrexate or cyclosporine**

Results



Pediatric patients receiving dupilumab had numerically greater improvements in BSA vs patients receiving methotrexate or cyclosporine

Results



Safety

	Dupilumab (n = 361)		Methotrexate (n = 154)		Cyclosporine (n = 153)		Total (N = 1,628)	
Patient with any AE[a]	**n (%)[a]**	**EAER/100PY[b]**	**n (%)[a]**	**EAER/100PY[b]**	**n (%)[a]**	**EAER/100PY[b]**	**n (%)[a]**	**EAER/100PY[b]**
TEAE	104 (28.8)	37.7	44 (28.6)	41.7	48 (31.4)	56.7	256 (19.3)	12.51
SAE	5 (1.4)	0.8	1 (0.6)	0.9	3 (2.0)	2.3	27 (2.0)	0.61
Treatment-related AE	4 (1.1)	0.8	4 (2.6)	5.1	6 (3.9)	4.1	188 (14.2)	7.80
AE leading to corrective treatment/therapy	2 (0.6)	0.5	3 (1.9)	1.3	10 (6.5)	5.9	30 (2.3)	1.05
AE leading to hospitalization	3 (0.8)	0.5	1 (0.6)	0.9	3 (2.0)	2.3	25 (1.9)	0.57
AE leading to death	0	0	0	0	0	0	0	0.00
AE leading to premature discontinuation from study	0	0	0	0	0	0	0	0.00
AE leading to treatment discontinuation	0	0	1 (0.6)	0.4	3 (2.0)	2.3	10 (0.8)	0.20
5-year cumulative discontinuation rates,[c] %	31.6		71.1		88.7		-	
Treatment exposure,[d] mean (SD), months	21.3 (17.41)		20.2 (16.88)		13.6 (13.22)		-	

[a]Calculated as the number of patients who reported an AE. [b]Calculated as number of new AEs occurring in exposure periods between the first dose and up to and including 30 days after the last dose of a specific therapy for AD divided by total patient-years (number of AEs/drug exposure time [100 patient-years]). [c]Proportion of patients who stopped the study out of all enrolled patients for the time period of this study. [d]Exposed duration (months) is defined for AD only and for time periods with no changes in dose, from baseline until end of follow-up, inclusive of both days. It was calculated as sum of treatment periods (end date – start date + 1)/30.4 per patient.

EAER/100PY, exposure-adjusted event rate per 100 patient-years; SAE, serious adverse event; TEAE, treatment-emergent adverse event.

Conclusion

Patients aged <12 years treated with **dupilumab** had a **numerically greater improvement** in clinician-reported AD signs and lower discontinuation rates compared with patients treated with **methotrexate** or **cyclosporine**