

ATOPIC DERMATITIS:

KEY LEARNINGS FROM

PHESI'S ANALYSIS

OF PHASE 3 CLINICAL TRIALS

JUNE 2025

OVERVIEW

Clinical development faces mounting pressure to deliver therapies quickly and cost-effectively. The stakes are highest for Phase 3 clinical trials, with success dictated by efficacy issues, safety concerns, and strategic and operational factors. Timely access to real-world patient data to enable informed decisions to be made about trial design, investigator site selection and enrollment can significantly impact trial success, and is vital for getting trials that aren't going to plan back on track.



ANALYSIS OF ATOPIC DERMATITIS PHASE 3 TRIALS

Phesi's analysis of industry-sponsored Phase 3 trials that have begun recruiting patients from January 2024, shows atopic dermatitis ranks second highest with 18 active trials (behind non-small cell lung cancer which has the largest number of phase 3 trials underway).

A closer look at the data highlights two key issues – firstly, there is potential to reduce patient burden by simplifying the design of atopic dermatitis trials; secondly, competition for investigator sites is intensifying as companies race against time to get new therapies to market.

REDUCING PATIENT BURDEN BY SIMPLIFYING TRIAL DESIGN

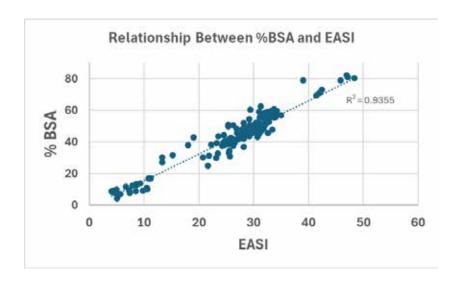
Using Trial Accelerator™, our award-winning AI-powered data platform, we have created a Digital Patient Profile for adult atopic dermatitis. This provides a statistical view of the patient population using key demographics including age, sex, comorbidities, outcome measures and concomitant medications. Digital Patient Profiles enable sponsors to design patient-centric trials, optimize the clinical development process and accelerate the commercialization of new drugs.



Phesi Digital Patient Profile: Adult Atopic Dermatitis		Digital Baseline Patient Characteristics	Data from Real World Sources	
			#pts	#cohorts
Demographic	Male	50%	82,316	264
Demographic	Female	51%	36,019	354
Demographic	Age (years) Mean ± SD	37.1 ± 14.0	88,991	703
Demographic	Weight (kg)	70.9 ± 15.9	9,479	176
Demographic	BMI ± kg/m2), Mean ± SD	26.2 ± 5.4	23,264	234
	Duration of AD	23.2 ± 14.3	37,741	234
	Diagnosis age	17.0 ± 18.1	1,910	15
Race & Ethnity	White	68%	42,616	298
Race & Ethnity	African	11%	36,242	233
Race & Ethnity	Asian	20%	34,557	233
Race & Ethnity	Hispanic	9%	10,338	66
Disease measure	EASI	29.5 ± 11.5	46,744	344
Disease measure	%BSA	37.8 ± 20.3	36,235	305
Disease measure	SCORAD	55.2 ± 13.0	17,579	224
Disease measure	DLQI	14.8 ± 6.8	31,521	205
Disease measure	POEM	17.0 ± 5.7	13,870	95
Disease measure	WPAI-AD	38.0 ± 27.1	8,484	60
IGA	IGA 0	12%	4,032	24
IGA	IGA 1	36%	4,231	26
IGA	IGA 2	25%	7,988	57
IGA	IGA 3	59%	22,708	171
IGA	IGA 4	36%	20,690	152
IGA	IGA 5	5%	2,666	23
Comorbidity	Asthma	28%	10,415	103
Comorbidity	Allergic rhinitis	35%	9,652	79
Medication	Topical treatment	45%	4,226	69
Medication	Systemic therapies	41%	3,156	54
Medication	Systemic immunosuppressants	27%	6,527	35
Medication	Corticosteroids	34%	5,583	26
Medication	Biologic therapies	9%	1,753	21
Medication	Cyclosporin	36%	827	19
Medication	Dupilumab	18%	1,440	17

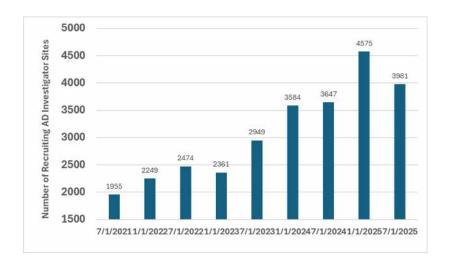
Further analysis shows that there is a near-perfect correlation between EASI (Eczema Area and Severity Index) and %BSA (percentage of affected body surface area). As EASI is a complicated disease score driven by multiple factors, and %BSA is a simple disease measure, this could present an opportunity to simplify trial design and reduce patient burden.





INTENSIFYING COMPETITION

Our data shows that atopic dermatitis trials could face increasingly intense enrollment challenges. In less than four years, recruiting atopic dermatitis trial sites have increased from 1,944 in July 2021 to 3,981 in June 2025. This 205% increase is way beyond the global clinical development capacity for atopic dermatitis. Growing problems with patient recruitment and enrollment can be seen in an extreme example at First OC Dermatology Research, Inc. in Fountain Valley, a village in California with a 55,000 population a which is currently recruiting patients for 14 atopic dermatitis trials.





HOW PHESI CAN SUPPORT PHASE 3 ATOPIC DERMATITIS CLINICAL TRIALS

Phesi is a leading clinical data science company. Our AI-powered Trial Accelerator leverages contextualized data from 167 million patients to simulate clinical development and accelerate commercialization for all disease areas.

Poor performing clinical trials stem from two evergreen problems – protocol design issues and a lack of precision in investigator site selection. We work in partnership with clients to solve these challenges using patient-centric analytics to drive timely decision making and deliver smarter trials and faster cures.

At the heart of our solutions is the Digital Patient Profile. From this we are able to derive a Patient Access Score, a unique performance measure which helps sponsors select the best performing investigator sites across 195 countries and eliminate non-active, non-enrolling investigator sites. As part of our site rescue services we evaluate a client's protocol synopsis, country and site list, and enrollment time aspirations to determine whether it's possible to achieve a

better outcome and what the best course action will be to maximize success using scenario planning.

For further information visit www.phesi.com.



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