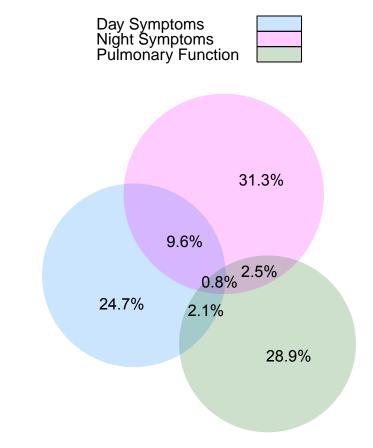


Day Symptoms Night Symptoms Pulmonary Function





Characteristic	ACE	ICATA	PROSE	p-value
	(n=546)	(n=419)	(n=478)	
Age - yr.	14 [13-16]	10 [8-14]	9 [7-11]	< 0.001
Male sex	288 (52.7%)	242 (57.8%)	303 (63.4%)	0.003
Race or ethnic group				< 0.001
Black	347 (63.6%)	252 (60.1%)	279 (58.4%)	
Hispanic	125 (22.9%)	155 (37.0%)	161 (33.7%)	
Other or mixed	74 (13.6%)	12 (2.9%)	38 (8.0%)	
Caretaker completed high school	358 (76.5%)	303 (74.1%)	340 (71.3%)	0.19
\geq household member employed	450 (82.4%)	302 (72.1%)	330 (69.0%)	< 0.001
Annual household income < \$15,000	262 (52.2%)	224 (53.7%)	262 (55.4%)	0.61
Duration of asthma – yr.	10.1 (4.3)	6.8 (3.9)	6.9 (3.5)	< 0.001
Total Serum IgE	262 [100-658]	240 [118-424]	254 [128-462]	0.10
Total # Positive Aeroallergen Skin Tests	5.0 [2.0-7.0]	5.00 [3.0-7.0]	4.0 [3.0-6.0]	< 0.001
Asthma Control				
C-ACT score, previous month, age 4-11 yr.	N/A	18.9 (4.07)	18.9 (4.10)	0.87
ACT score, previous month, age ≥ 12 yr.	18.2 (4.19)	18.8 (4.22)	19.1 (4.10)	0.04
Asthma-related symptoms –days/2 weeks				
Wheezing	4.5 (4.13)	4.0 (3.91)	3.6 (3.88)	0.001
Interference with activity	3.3 (4.09)	2.7 (3.35)	2.6 (3.59)	0.002
Nighttime sleep disruption	2.7 (3.69)	2.1 (3.14)	1.9 (3.08)	< 0.001
Lung function				
FEV_1 - % predicted value	92.1 (16.6)	92.1 (17.1)	90.5 (17.2)	0.23
FEV ₁ : FVC x 100	77.8 (9.42)	77.0 (9.90)	77.4 (10.2)	0.46
Asthma healthcare use in 6 mo. prior to enrollment*				
\geq 1 hospitalization (participant or parent self-reported)	80 (14.7%)	104 (24.8%)	96 (20.1%)	< 0.001
\geq 1 unscheduled visit (participant or parent self-reported)	375 (68.7%)	328 (78.3%)		0.001

Table E1 - Characteristics of Study Participants at Screening Visit from Three ICAC Clinical Trials

Values are mean (standard deviation), median [interquartile range] or number (percent)

N/A (Not Applicable)

* In PROSE hospitalizations where collected with a 1-year look back; unscheduled visits were not collected.

(A)	Control Level	Screening	Randomization	1st post*	End of study *
	1	124 (22.7%)	385 (70.5%)	193 (73.9%)	177 (72.8%)
	2	109 (20.0%)	93 (17.0%)	37 (14.2%)	29 (11.9%)
ACE	3	125 (22.9%)	36 (6.6%)	18 (6.9%)	22 (9.1%)
	4	188 (34.4%)	32 (5.9%)	13 (5.0%)	15 (6.2%)
	Ν	546	546	261	243
	Mean (SD)	2.7 (1.2)	1.5 (0.9)	1.4 (0.8)	1.5 (0.9)
	1	116 (27.7%)	214 (51.1%)	88 (48.4%)	106 (62.7%)
	2	76 (18.1%)	97 (23.2%)	35 (19.2%)	33 (19.5%)
ICATA	3	100 (23.9%)	52 (12.4%)	33 (18.1%)	17 (10.1%)
	4	127 (30.3%)	56 (13.4%)	26 (14.3%)	13 (7.7%)
	Ν	419	419	182	169
	Mean (SD)	2.6 (1.2)	1.9 (1.1)	2.0 (1.1)	1.6 (0.9)
	1	68 (13.3%)	265 (51.7%)		
	2	162 (31.6%)	133 (25.9%)		
PROSE	3	133 (25.9%)	67 (13.1%)		
	4	150 (29.2%)	48 (9.4%)		
	Ν	513	513		
	Mean (SD)	2.7 (1.0)	1.8 (1.0)		

<u>Table E2</u> – (A) Asthma control level and (B) treatment steps by Clinical Trial by Visit

* Usual care only for the double-blind phase.

(B)	Treatment Step	Screening	Randomization	1st post*	End of study*
	0		4 (0.7%)	23 (8.8%)	43 (17.7%)
	1	86 (15.8%)	58 (10.6%)	25 (9.6%)	28 (11.5%)
	2	100 (18.3%)	101 (18.5%)	34 (13.0%)	36 (14.8%)
	3	74 (13.6%)	78 (14.3%)	33 (12.6%)	40 (16.5%)
ACE	4	101 (18.5%)	76 (13.9%)	45 (17.2%)	20 (8.2%)
	5	105 (19.2%)	95 (17.4%)	45 (17.2%)	20 (8.2%)
	6	80 (14.7%)	134 (24.5%)	56 (21.5%)	56 (23%)
	Ν	546	546	261	243
	Mean (SD)	3.5 (1.7)	3.8 (1.8)	3.6 (1.9)	3.0 (2.2)
	0				22 (13.0%)
	1	49 (11.7%)	44 (10.5%)	22 (12.2%)	20 (11.8%)
	2	61 (14.6%)	69 (16.5%)	30 (16.6%)	22 (13.0%)
	3	90 (21.5%)	80 (19.1%)	30 (16.6%)	25 (14.8%)
ICATA	4	87 (20.8%)	72 (17.2%)	33 (18.2%)	25 (14.8%)
	5	54 (12.9%)	83 (19.8%)	27 (14.9%)	28 (16.6%)
	6	78 (18.6%)	71 (16.9%)	39 (21.5%)	27 (16.0%)
	Ν	419	419	182	169
	Mean (SD)	3.6 (1.6)	3.7 (1.6)	3.7 (1.7)	3.2 (2.0)
	0				
	1				
PROSE	2	167 (32.6%)	105 (20.5%)		
	3	120 (23.4%)	101 (19.7%)		
	4	110 (21.4%)	112 (21.8%)		
	5	116 (22.6%)	195 (38%)		
	6				
	Ν	513	513		
	Mean (SD)	3.3 (1.2)	3.8 (1.2)		

* Placebos only for the double-blind phase.

Supplemental material figure legends

<u>Figure E1</u> - Venn diagrams displaying contribution of each ACET impairment domain measurement from all included study visits to control levels 2-4 for each clinical trial. Numerals are numbers of times measure contributed to control.

<u>Figure E2</u> - Venn diagrams displaying contribution of each ACET impairment domain measurement from all included study visits by control level for all three ICAC trials combined. Numerals are numbers of times measure contributed to control level.