TEXAS A&M UNIVERSITY

Data Visualization: the Clinical Trial of AMG 827

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Investigation of The Patient Population

	Phase II		Phase III	
Demographic Factors	Treatment (n=160)	Placebo (n=38)	Treatment (n=1522)	Placebo (n=309)
Weight		*p = 0.0972		p = 0.7772
	86.9290	93.3106	91.1601	91.5351
PASI		p = 0.7472		p = 0.8526
	18.8947	19.2438	20.5955	20.6899
Age		p = 0.7625		p = 0.7036
<20	0	0	44	7
[20, 40)	74	19	445	92
[40, 60)	72	14	834	170
[60, 80)	14	5	190	38
>=80	0	0	9	2
Sex		p = 0.4808		p = 0.0831
Female	55	16	472	112
Male	105	22	1050	197
sPGA		p = 0.0172		p = 0.0211
2	50	8		
3	44	20	816	178
4	41	4	619	104
5	25	6	87	27

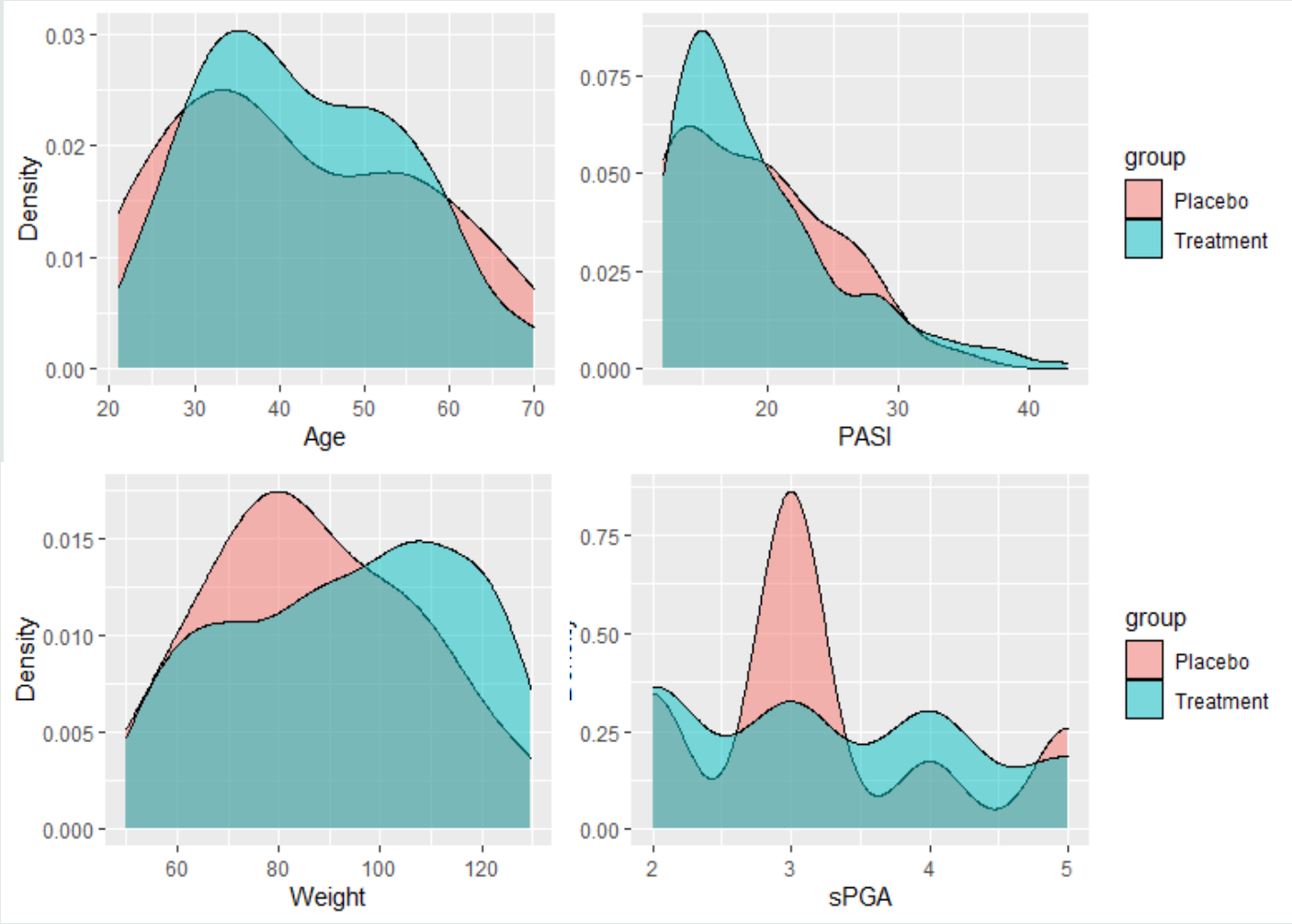
*The p-values were obtained via t-test or chi-squared test.
The number showed in weight and PASI are mean, while in Age, sex, sPGA are N.

Except sPGA, the patient population was balanced across different demographic factors: PASI, age, and sex in both Phase II and Phase III.

Attention: While showing p-values for multiple tests comparing placebo with treatment arms - is multiplicity. #We may end up inflating the Type I error, if we do not plan for multiplicity.

Investigation of The Patient Population

By drawing density plot, we are able to see the population distribution of the four groups.

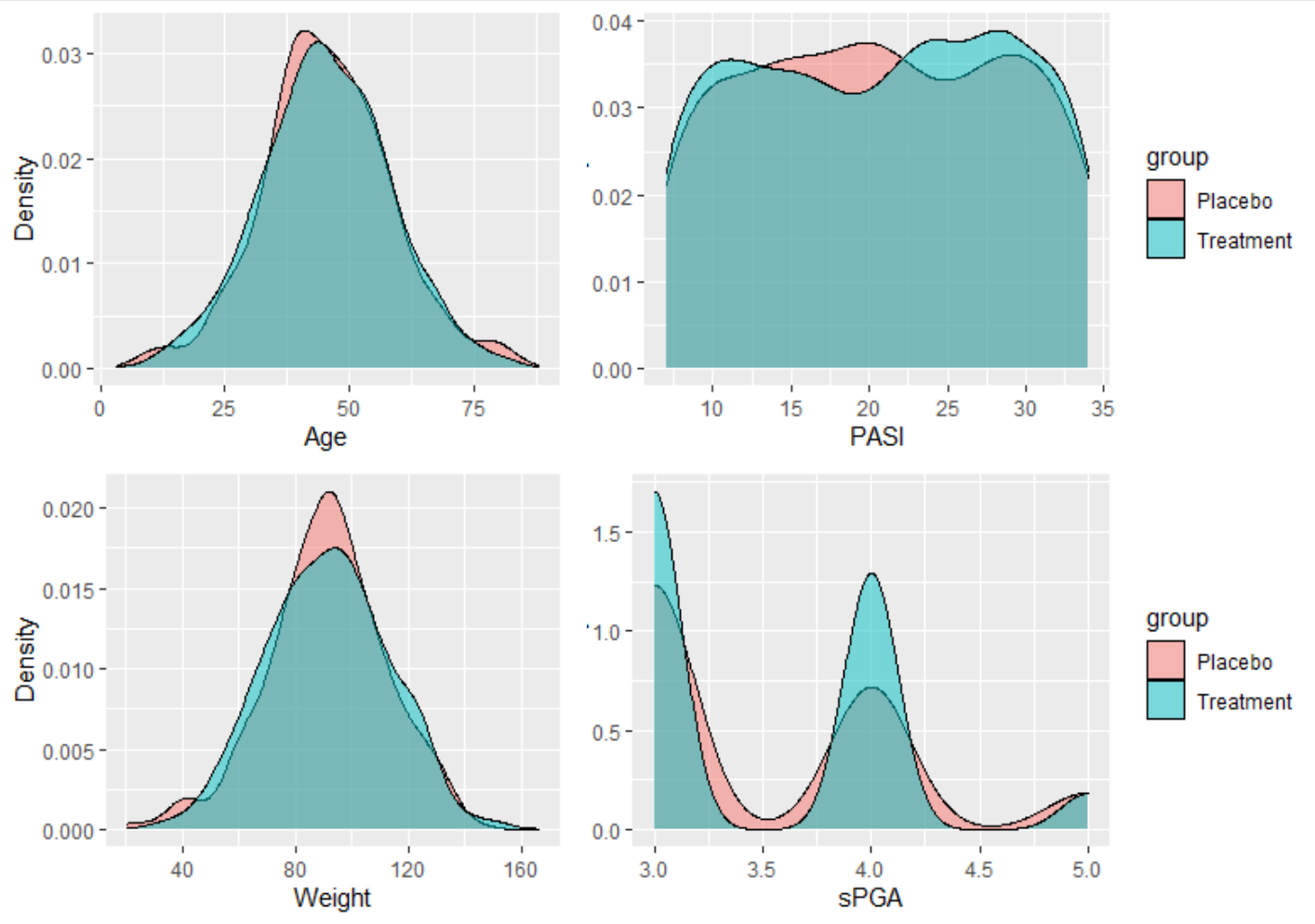


Phase II:

We could easily see that except the distribution of sPGA, the patient population were similarly distributed among the demographic factors of gender, age and PASI.

Investigation of The Patient Population

By drawing density plot, we are able to see the population distribution of the four groups.

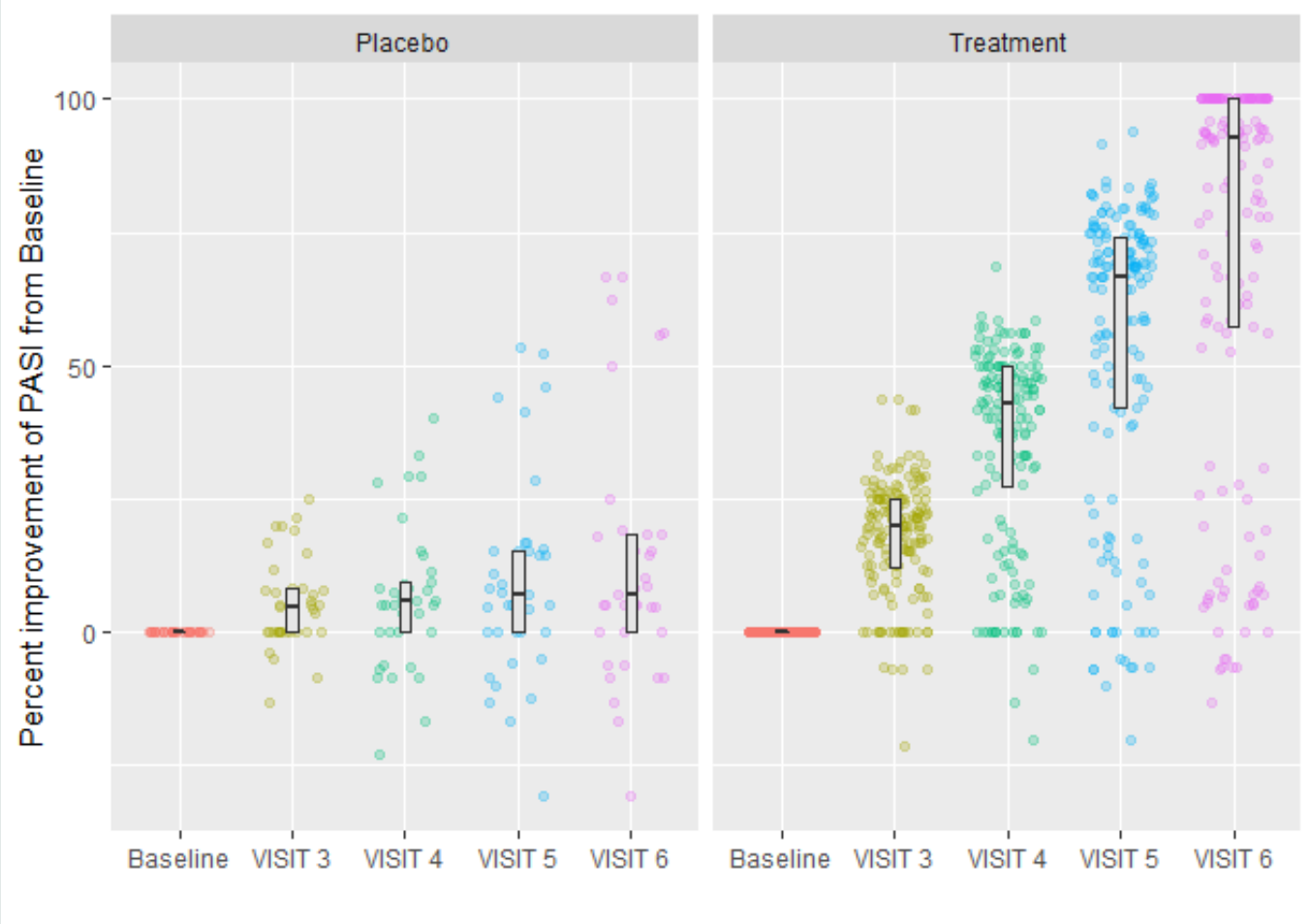


Phase III:

We could easily see that except the distribution of sPGA, the patient population were similarly distributed among the demographic factors of gender, age and PASI.

Percent Improvement of PASI at The End of The Trial

Overall comparison between the improvement of placebo and treatment group: The four doses were combined and set as a treatment group.



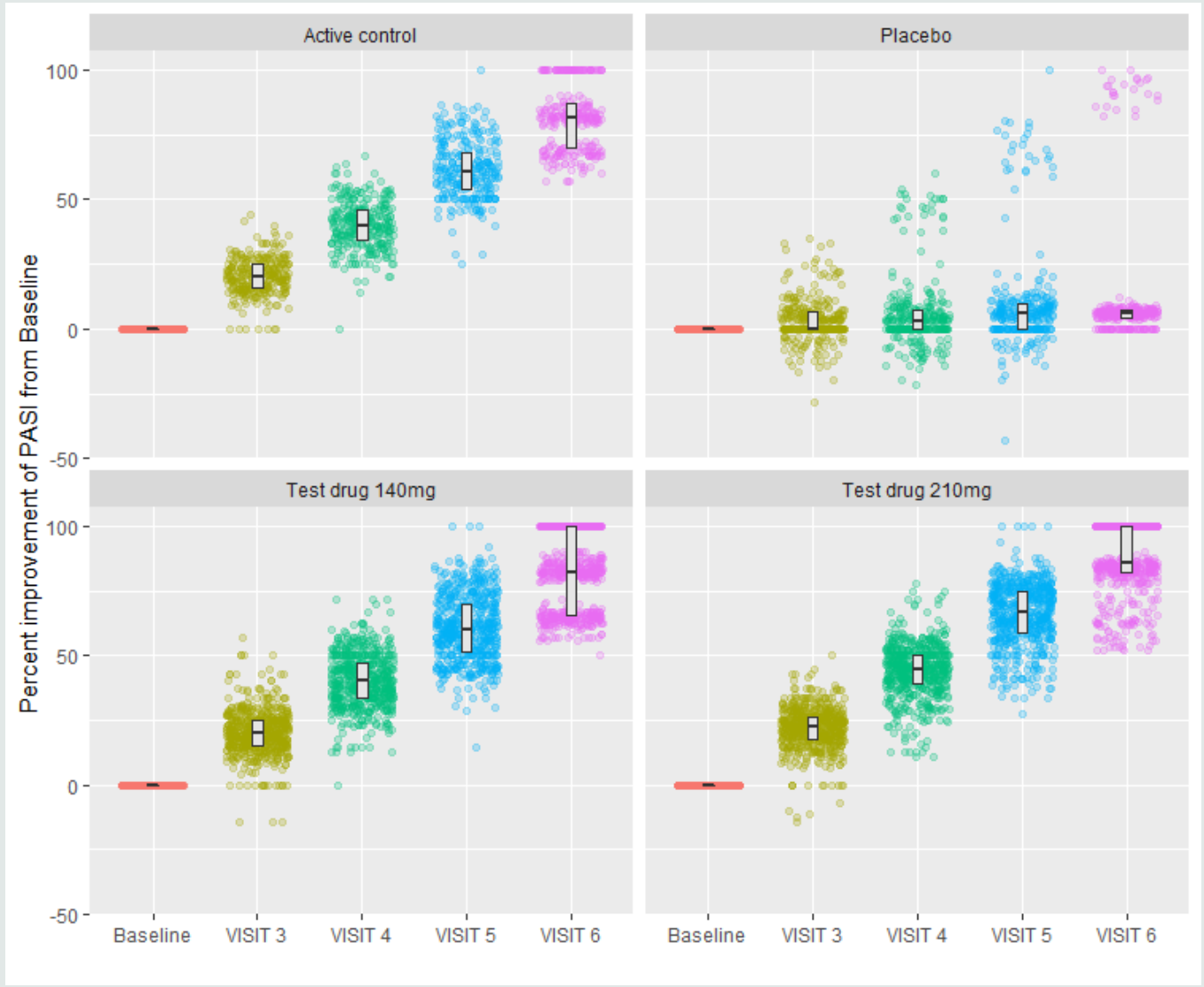
The y-axis stands for the percent improvement of PASI from baseline.

At the end of Phase II, both the placebo and treatment group have improved compared with the beginning.

Percent Improvement of PASI at The End of The Trial

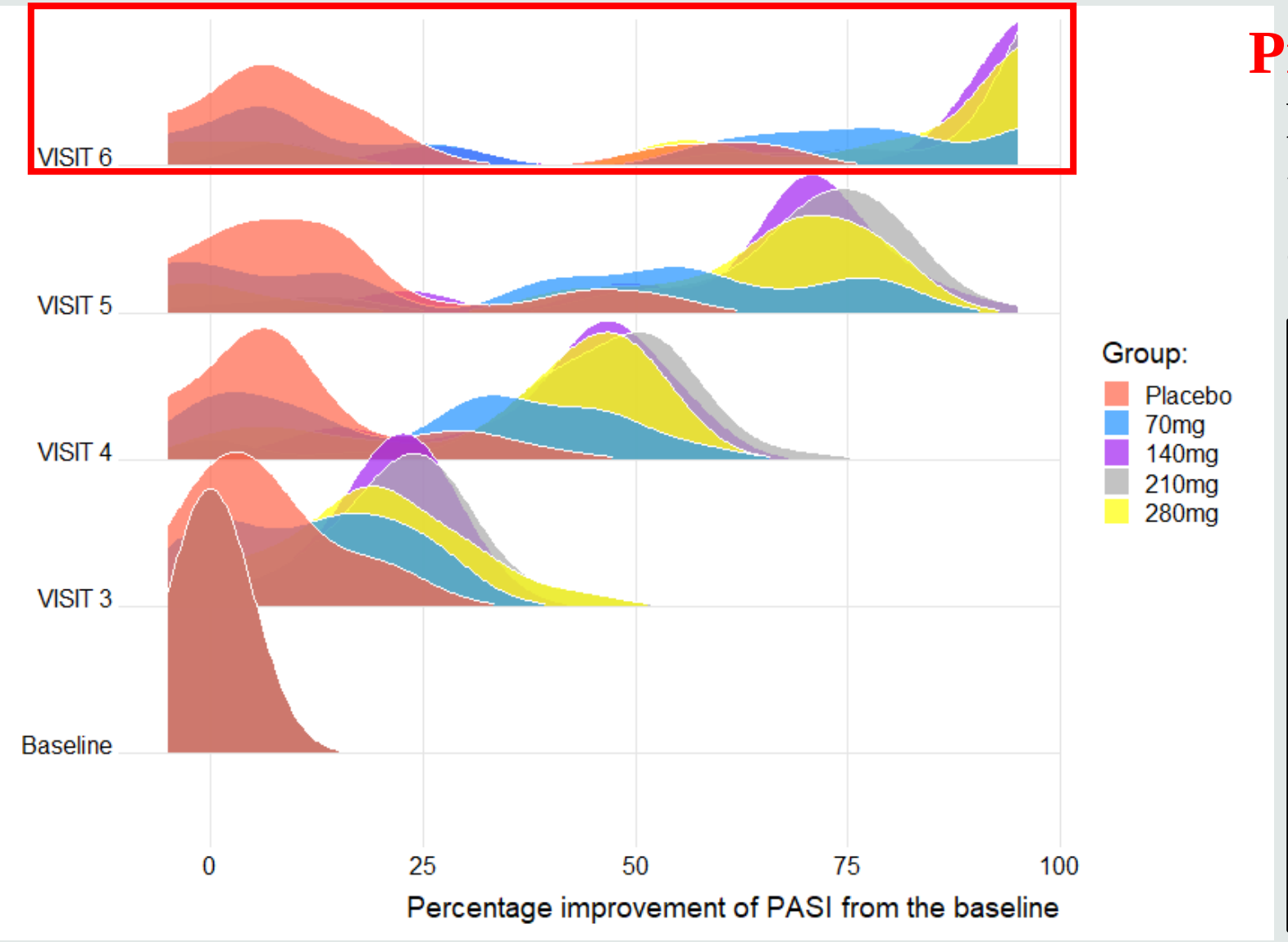
At the end of Phase II, the test drug 140mg, 210mg and 280mg were significantly improved from the baseline in each visit, the 140mg and 210mg are highly condensed among the five groups.

Percent Improvement of PASI at The End of The Trial



At the end of Phase III, comparing with the placebo, the test drug were significantly improved from the baseline in each of the visit.

Phase II: Improvement for The Primary Endpoint VS. The Secondary Endpoint



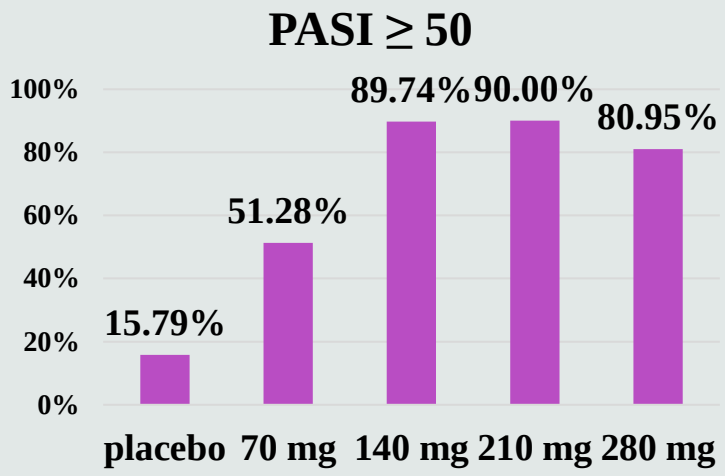
Primary endpoints:

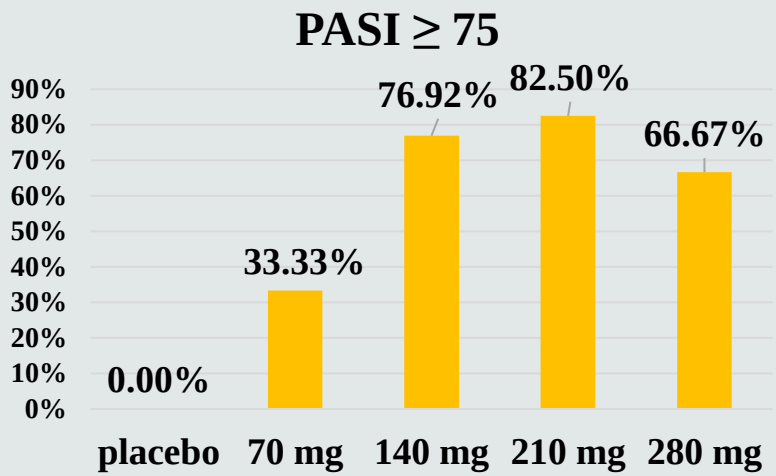
Percent improvement from baseline in PASI at week 12

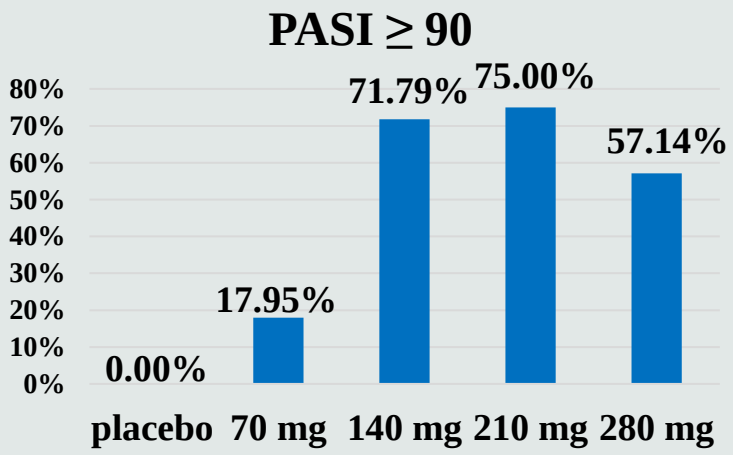
The percentage improvement of PASI from the baseline have been increasing for all treatment groups since the visit2 (baseline).

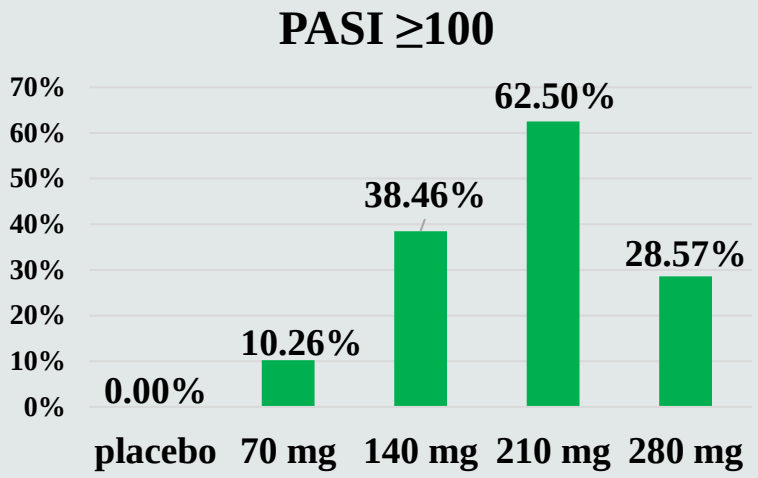
Phase II: Improvement for The Primary Endpoint VS. The Secondary Endpoint

Secondary endpoint: PASI 50, PASI 75, PASI 90 and PASI 100.







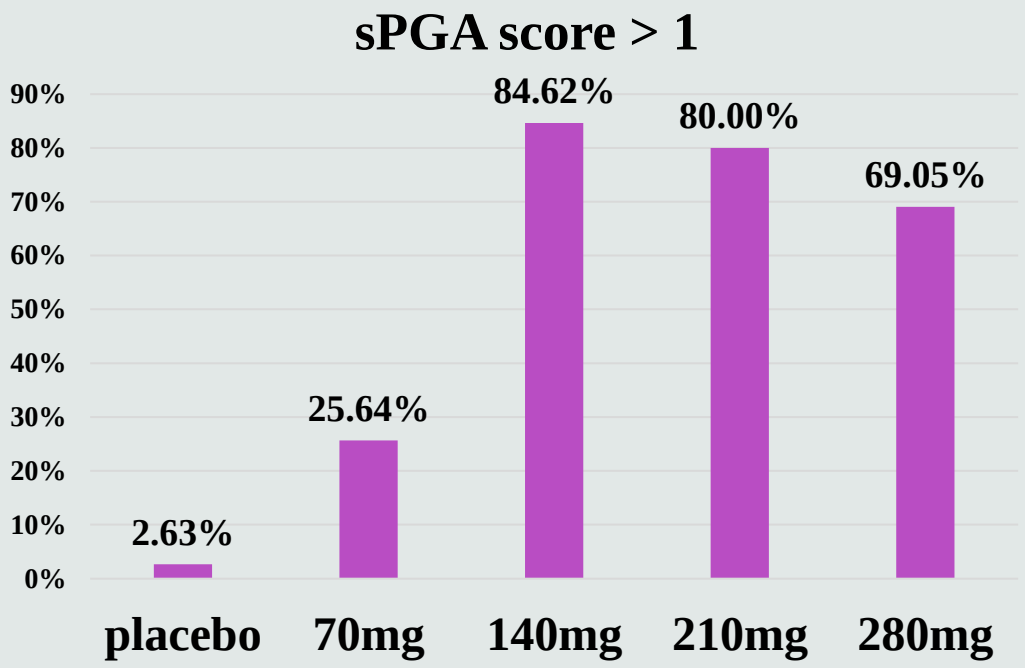


As the density plot shown in the previous slide, the 140mg, 210mg and 280mg treatment group have the higher percentage of the PASI 50/75/90/100 at week 12.

Phase II: Improvement for The Primary Endpoint VS. The Secondary Endpoint

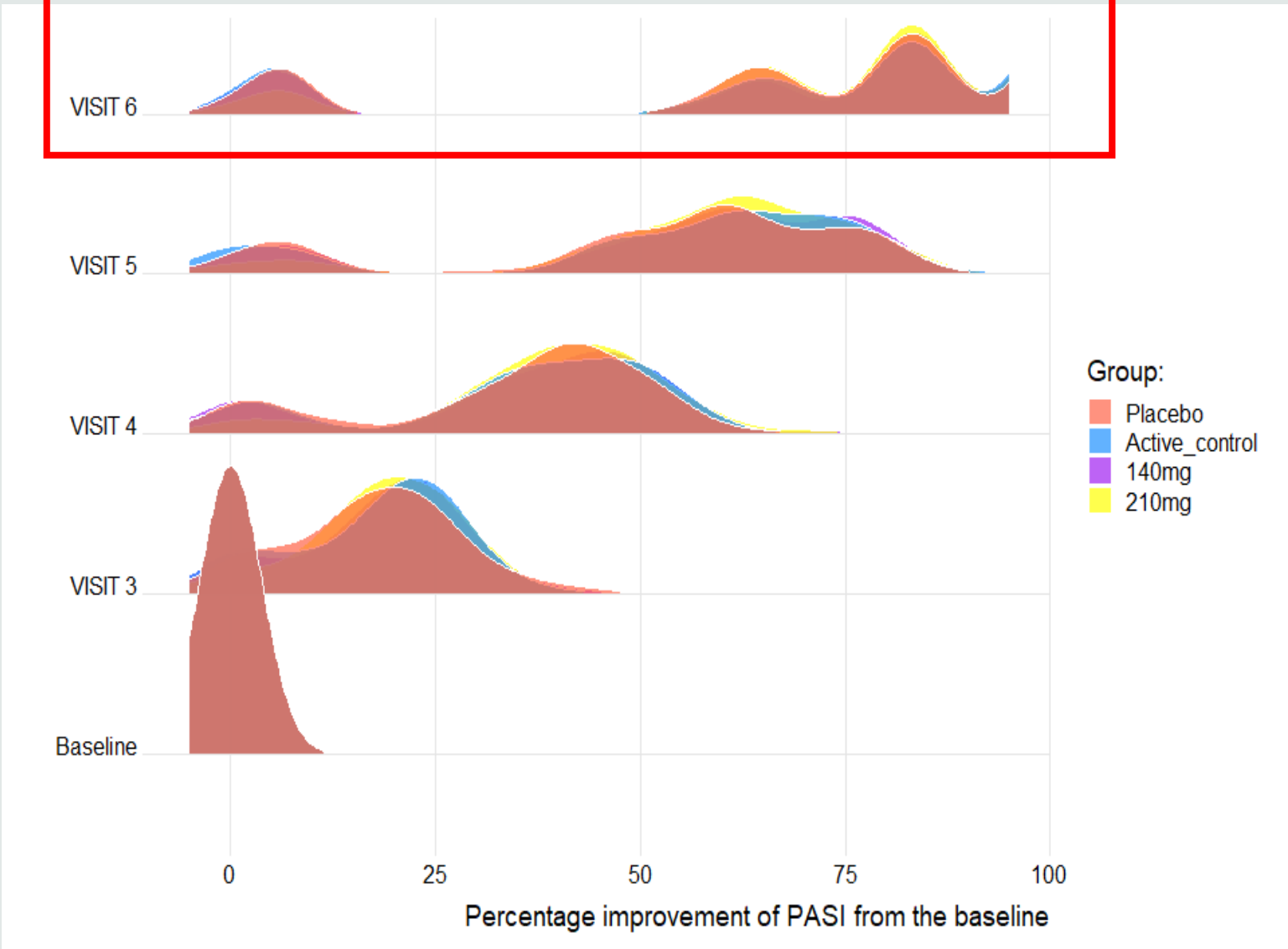
Secondary endpoints:

sPGA score at week 12



The patient who take 140mg has the highest percentage of the sPGA score (>1) among four treatment groups.

Phase III: Improvement for The Primary Endpoint VS. The Secondary Endpoint

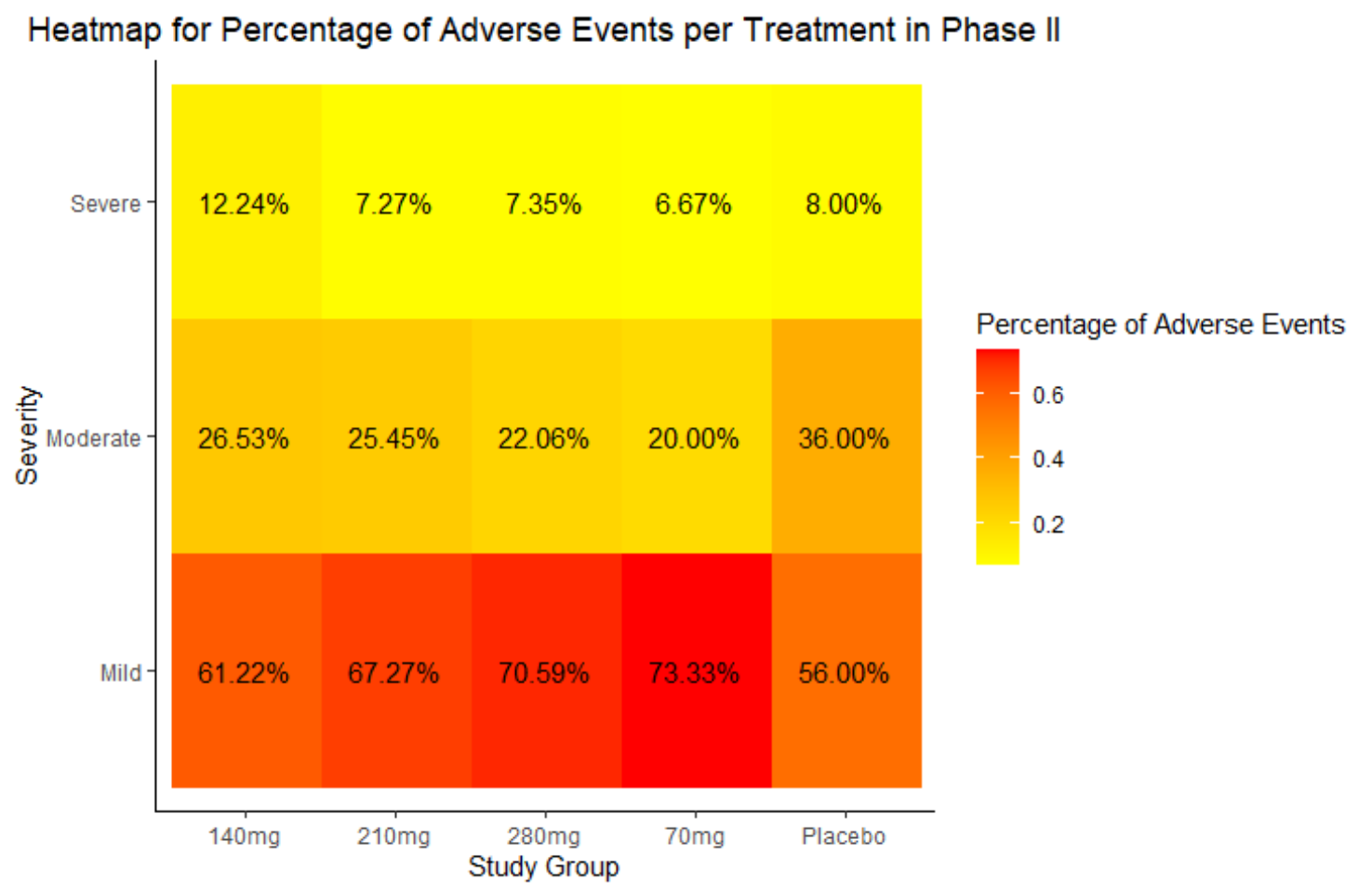


Primary endpoints:

Percent improvement from baseline in PASI at week 12

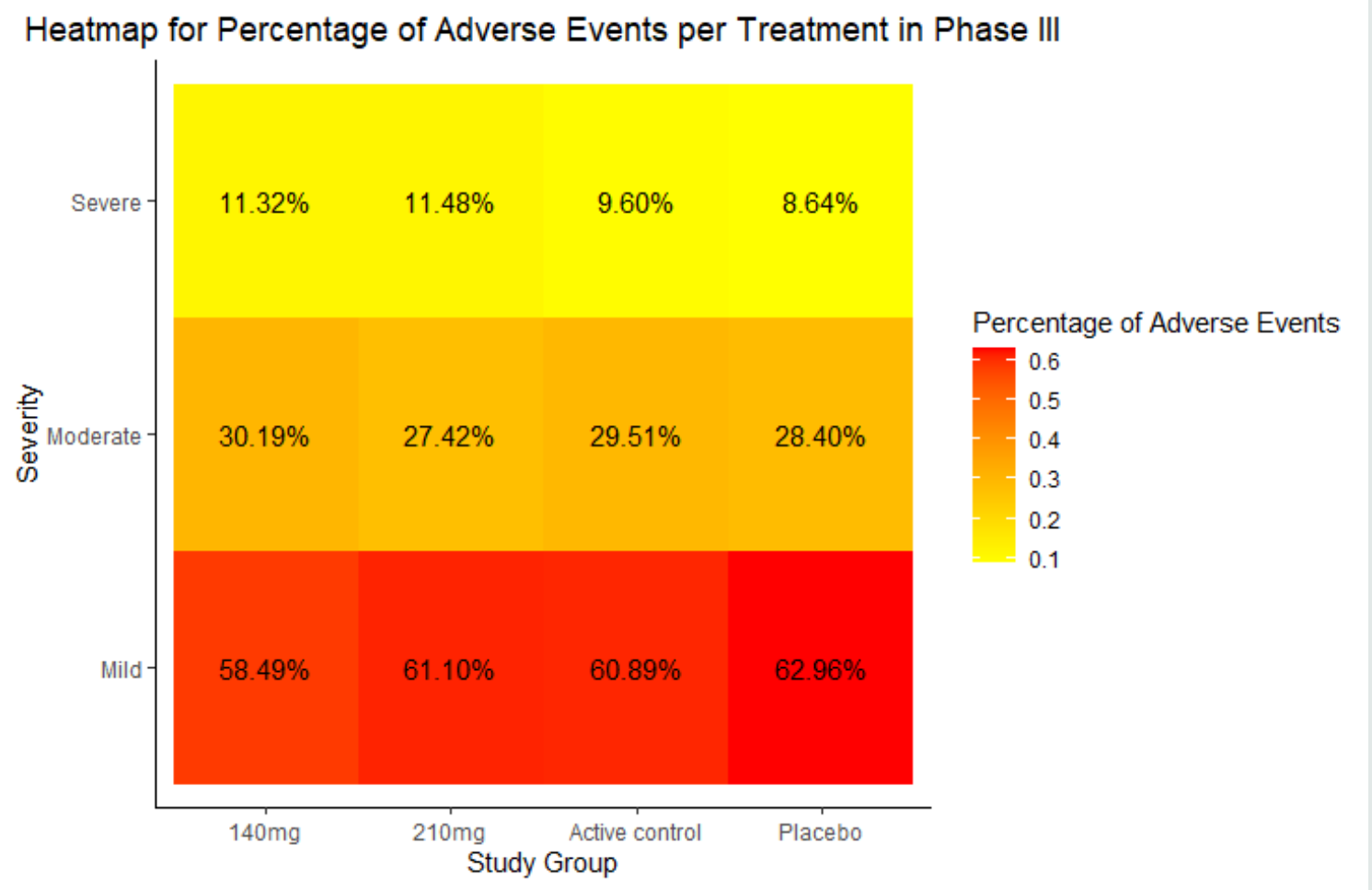
At week12, PASI 50 - PASI 90 have the most density of percentage improvement among four groups.

Adverse Event in Phase II



Severity in mild have the highest percentage of adverse event among all the groups.

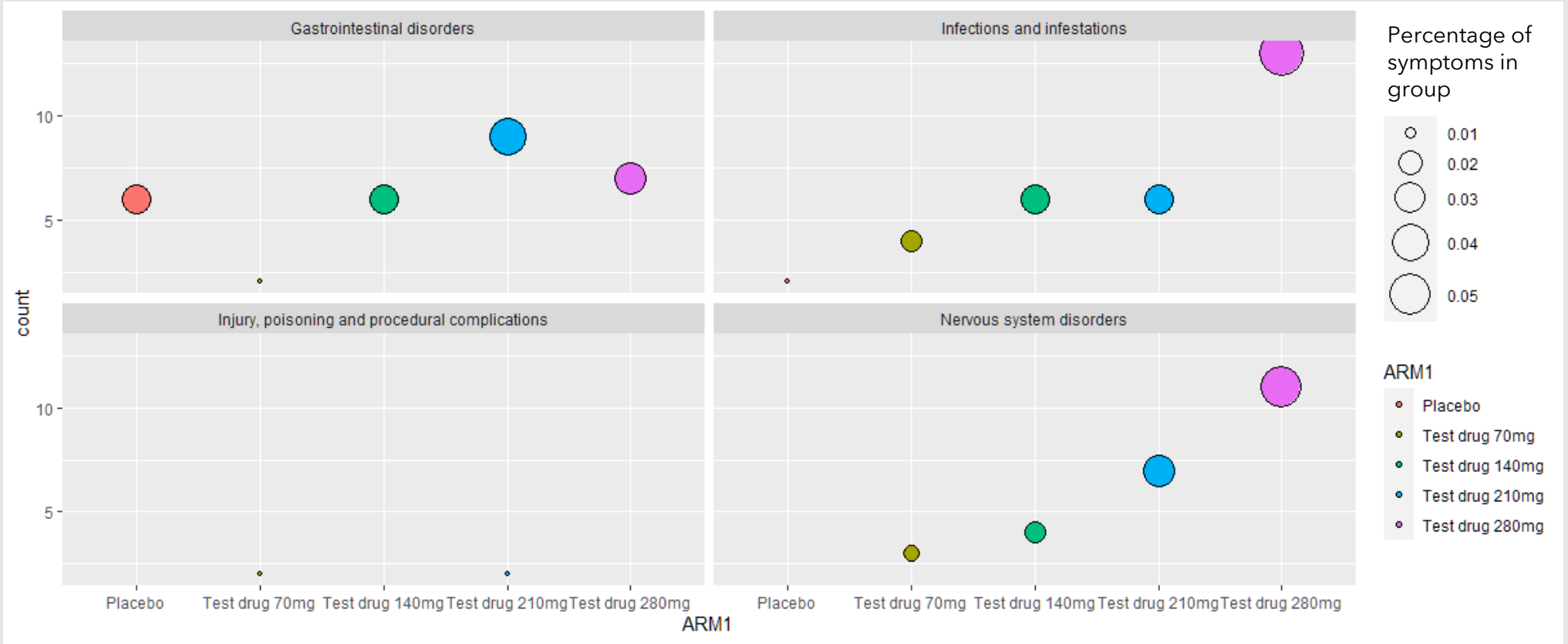
Adverse Event in Phase III



The patients received 210mg drug have the highest number of both mild and severe adverse events among treatment groups.

Investigation on A Specific Type of Adverse Event

Bubble plots for different symptoms with high frequency in Phase II.



Patient who takes 210 mg and 280 mg doses are more likely to experience Gastrointestinal disorder, Infections and infestations.

Conclusion

1. The patient population was balanced across different demographic factors such as gender, age, weight and PASI in both Phase II and Phase III.

2. Both treatment and placebo group were improved from the baseline at the end of the Phase II and Phase III.

3. There is improvement for the primary endpoint reflected in treatment groups similarly across the secondary endpoint, especially in the 140mg, 210mg and 280mg treatment groups in Phase II and Phase III.

4. Patients with high dose are more likely to experience adverse events.

5. In Phase II, the patients with high dose have higher proportions of symptoms such as infections and infestations and nervous system disorder.

Results

- In phase II, we can compare the proportion for symptoms for groups.

- After considering the efficacy and safety issues, we might use drug 140mg or 210mg in the Phase IV.

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Thank you for listening!

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