

RV144 Results

On October 20, 2009, expanded data analyses by RV144 investigators were presented at the AIDS Vaccine 2009 conference and published in the *New England Journal of Medicine* (<http://content.nejm.org/cgi/content/full/NEJMoa0908492>). These included a comparison of rates of infections in vaccine and placebo recipients, using three approaches: intent to treat (ITT), modified intent to treat (mITT) and per protocol (PP) analyses. Each of these analyses looked at a slightly different number of individuals and yielded slightly different results. One of the most important facets of

the Thai trial results is that all three analyses—ITT, mITT and PP—show the same trend: in every case, fewer infections were observed in the vaccine arm compared to the placebo arm. However, the wide confidence intervals around the point estimates of vaccine efficacy in each of the analyses indicate a fair amount of uncertainty about how much the vaccine may have reduced the risk of HIV acquisition for participants who were given the active vaccine. This underscores the need to conduct further research and analyses to help gain a greater understanding of the findings. The results from each type of analysis are below.

THAI TRIAL DATA	Analysis		
	ITT	mITT	PP
Participants	16,402	16,395	12,542
Infections in vaccine group	56	51	36
Infections in placebo group	76	74	50
Point estimate of vaccine efficacy	26.4%	31.2%	26.2%
95% Confidence Interval	-4.0, 47.9	1.1, 51.2	-13.3, 51.9
P-value	0.08	0.04	0.16
Statistically significant?	No	Yes	No

For more on the different statistical analyses, please see AVAC's document on understanding the Thai trial results, available at www.avac.org/thaitrial.

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