

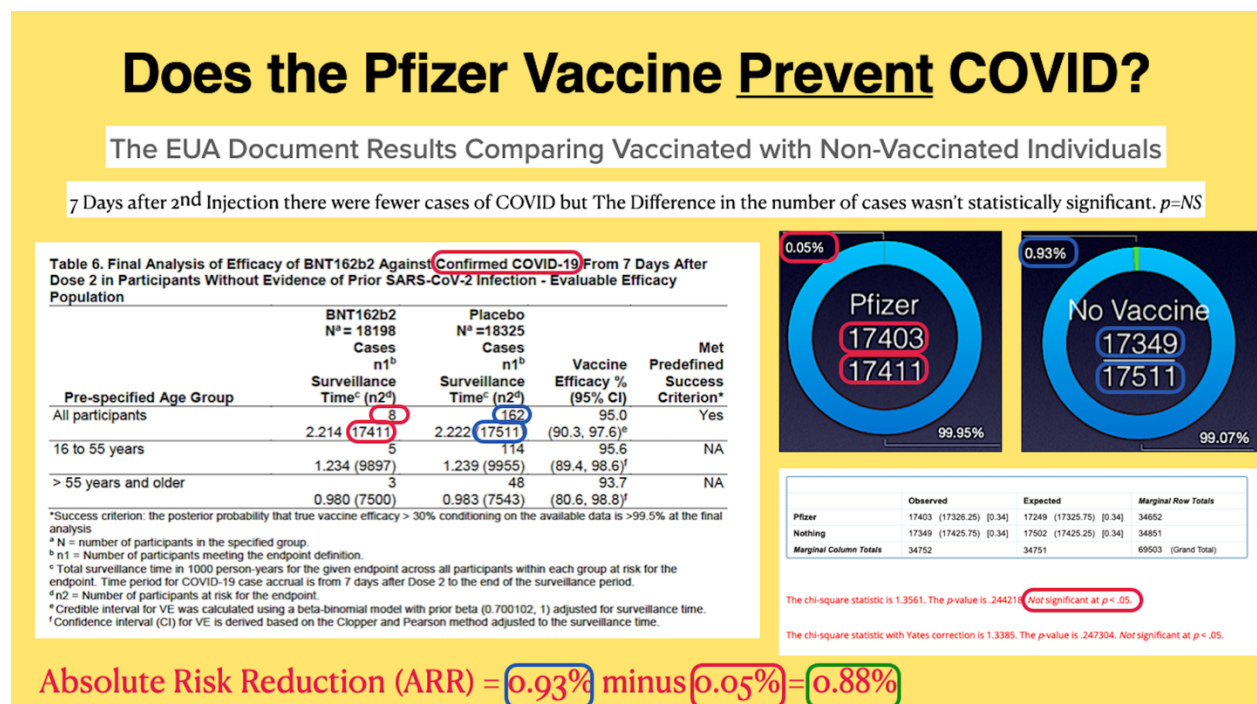
## Is There a Statistically Significant Difference Between Vaccinated and Un-vaccinated Individuals for Either Post-Infection Coronavirus Disease (COVID-19)?

When scientist-physicians want to know if a treatment, including the Pfizer, Moderna and Janssen Drug Vaccine Biologics, works, we must do more than merely look at the numbers. We must statistically compare the results of those treated (vaccinated) with those not treated (unvaccinated) to determine if these differences are significant or meaningless. This avoids giving treatments to people that are not scientifically beneficial.

There are a variety of statistical methods that can be used and selection of the correct statistical analysis is determined by the type of research conducted. This includes taking into account what type of numbers we are using. Ordinate numbers of numbers with units attached (e.g. inches, pounds, milligrams/liter, millimeters of mercury, et cetera.). Alternatively, when we count or identify something we use cardinal or nominal numbers to define how many in that group. In this instance a person who is 42-year-old Caucasian female and a 27-year-old Hispanic male and a 59-year-old Asian female, all have the same value; one for each of them.

Cardinal or nominal numbers can be statistically compared using either correlation, which does not provide cause and effect, or Chi-Square analysis. Chi-square analysis allows the statistical comparison between treatment by asking a fundamental question. If there is no difference (null hypothesis always applied to scientific research) between the two groups, then the expected outcomes (no difference between groups) should match the observed outcomes from the study.

When the EUA documents were used for the statistical analysis of the Pfizer, Moderna, and Janssen Drug Vaccine Biologics, and the Chi-Square analysis of the results published in those EUA documents was analyzed for the Pfizer vaccine as shown in the following graphic, there was no statistical difference between vaccinated and un-vaccinated people diagnosed with having COVID-19. To be statistically different (a benefit for people being vaccinated) the “p (probability)-value” must be less than or equal to less than 5 times per hundred people. This is the scientific definition of statistical benefit and is written as “ $p \leq 0.05$ ”. In the graphic the p-value was 0.224418 and is NOT statistically significant; i.e. there is no statistical difference in the number of people diagnosed with COVID who were vaccinated when compared with the non-vaccinated group of people.



When this same approach is taken to the Moderna EUA results, there is no statistical difference between vaccinated and non-vaccinated individuals with a p-value of  $p=0.138706$ .

## Does the Moderna Vaccine Prevent COVID?

The EUA Document Results Comparing Vaccinated with Non-Vaccinated Individuals

14 Days after 2<sup>nd</sup> Injection there were fewer cases of COVID but The Difference in the number of cases wasn't statistically significant.  $p=NS$

Primary Endpoint: COVID-19 (per adjudication committee assessment)	Vaccine Group N=13934		Placebo Group N=13883		Vaccine Efficacy (VE) % (95% CI)**	Met Predefined Success Criterion***
	Cases n (%)	Incidence Rate per 1,000 person-years*	Cases n (%)	Incidence Rate per 1,000 person-years*		
All participants	11 (<0.1)	3.328	185 (1.3)	66.510	94.1% (89.3%, 96.8%)	Yes
18 to <65 years <sup>1</sup>	7/10551 (<0.1)	2.875	156/10521 (1.5)	64.625	95.6%; (90.6%, 97.9%)	NA
65 years and older <sup>2</sup>	4/3583 (0.1); 4.595	2.875	29/3552 (0.8); 33.728	64.625	86.4%; (61.4%, 95.5%)	NA

Moderna  
13923  
13934  
99.92%

No Vaccine  
13698  
13883  
98.67%

	Observed	Expected	Marginal Row Totals
Moderna	13923 (13836) [0.55]	13740 (13836) [0.55]	27672
Nothing	13698 (13785) [0.55]	13872 (13785) [0.55]	27570
Marginal Column Totals	27621	27621	55242 (Grand Total)

The chi-square statistic is 2.1923. The p-value is .138706. Not significant at  $p < .05$ .

The chi-square statistic with Yates correction is 2.1671. The p-value is .140989. Not significant at  $p < .05$ .

Absolute Risk Reduction (ARR) = 1.33% minus 0.08% = 1.25%

When this same approach is used to determine if there is a statistically significant reduction in COVID cases among people vaccinated with the Janssen vaccine, the 2-week (14-day) data shows a statistical benefit with a p-value of  $p=0.020258$ .

## At 14-Days Does the Janssen Vaccine Prevent COVID?

The EUA Document Results Comparing Vaccinated with Non-Vaccinated Individuals

14 Days after the Injection there were fewer cases of COVID & The Difference in the number of cases was statistically significant.  $p \leq 0.05$

Baseline SARS-CoV-2 Serostatus <sup>a</sup>	Onset at Least 14 Days			Onset at Least 28 Days		
	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE% (95% CI)	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE% <sup>b</sup> (95% CI)
Regardless of baseline SARS-CoV-2 status	176 (21636) 3450.2	513 (21574) 3409.8	66.1% (59.7, 71.6)	114 (21424) 3436.3	326 (21199) 3385.9	65.5% (57.2, 72.4)
Positive	3 (2122) 336.3	4 (2030) 320.8	28.5% (-322.8, 89.5)	1 (2118) 336.1	2 (2021) 320.0	
Negative	173 (19514) 3113.9	509 (19544) 3089.1	66.3% (59.9, 71.8)	113 (19306) 3100.3	324 (19178) 3065.9	65.5% (57.2, 72.4)

Source: Sponsor tables GEFPE07A, GEFPE07C  
<sup>a</sup>N=Total number of participants at risk per category  
<sup>b</sup>Based on serological test at baseline  
<sup>c</sup>If fewer than 6 cases are observed for an endpoint then the VE is not shown

Janssen  
21460  
21636  
99.19%

No Vaccine  
21061  
21574  
97.62%

	Observed	Expected	Marginal Row Totals
Johnson & Johnson	21460 (21290.75) [1.35]	21121 (21290.25) [1.35]	42581
Nothing	21061 (21230.25) [1.35]	21399 (21229.75) [1.35]	42460
Marginal Column Totals	42521	42520	85041 (Grand Total)

The chi-square statistic is 5.3895. The p-value is .020258. Significant at  $p < .05$ .

The chi-square statistic with Yates correction is 5.3577. The p-value is .020631. Significant at  $p < .05$ .

N.B. On page 6 of the EUA,  
 Absolute Risk Reduction (ARR) = 2.38% minus 0.81% = 1.57%

However, two weeks later at 4-weeks (28-days), that benefit was gone with a p-value of  $p=0.138761$ .

# At 28-Days Does the Janssen Vaccine Prevent COVID?

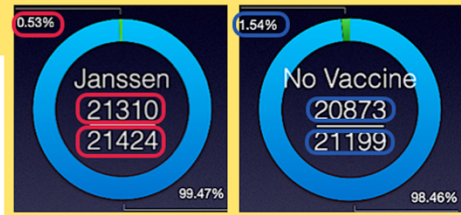
The EUA Document Results Comparing Vaccinated with Non-Vaccinated Individuals

28 Days after the Injection there were fewer cases of COVID but The Difference was NO LONGER statistically significant.  $p=NS$

Table 14. Vaccine Efficacy of First Occurrence of Moderate to Severe/Critical COVID-19 Including Non-centrally Confirmed Cases, With Onset at Least 14 or at Least 28 Days After Vaccination, by Baseline SARS-CoV-2 Status<sup>a</sup>, Per Protocol Set

Baseline SARS-CoV-2 Serostatus <sup>a</sup>	Onset at Least 14 Days			Onset at Least 28 Days		
	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE% (95% CI)	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE% <sup>b</sup> (95% CI)
Regardless of baseline SARS-CoV-2 status	176 (21636) 3450.2	513 (21574) 3409.8	66.1% (59.7, 71.6)	114 (21424) 3436.3	326 (21199) 3385.9	65.5% (57.2, 72.4)
Positive	3 (2122) 336.3	4 (2030) 320.8	28.5% (-322.8, 89.5)	1 (2118) 336.1	2 (2021) 320.0	
Negative	173 (19514) 3113.9	509 (19544) 3089.1	66.3% (59.9, 71.8)	113 (19306) 3100.3	324 (19178) 3065.9	65.5% (57.2, 72.4)

Source: Sponsor tables GEPPE07A, GEPPE07C  
 N=Total number of participants at risk per category  
<sup>a</sup>Based on serological test at baseline  
<sup>b</sup>If fewer than 6 cases are observed for an endpoint then the VE is not shown



	Observed	Expected	Marginal Row Totals
Johnson & Johnson	21310 (21202.5) [0.55]	21094 (21201.5) [0.55]	42404
Nothing	20873 (20980.5) [0.55]	21087 (20978.5) [0.55]	41960
Marginal Column Totals	42183	42181	84364 (Grand Total)

The chi-square statistic is 2.1916. The p-value is .138761. Not significant at  $p < .05$ .

The chi-square statistic with Yates correction is 2.1713. The p-value is .140607. Not significant at  $p < .05$ .

Absolute Risk Reduction (ARR) = 1.54% minus 0.53% = 1.01%

In brief, while there are differences between vaccinated and unvaccinated individuals who were diagnosed as having COVID-19, the differences are NOT statistically significant.

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