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<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.

Does the Pfizer Vaccine Prevent COVID?

The EUA Document Results Comparing Vaccinated with Non-Vaccinated Individuals

7 Days after 2nd Injection there were fewer cases of COVID but The Difference in the number of cases wasn't statistically significant. p=NS

Table 6. Final Analysis of Efficac; Dose 2 in Participants Without Exponents Population Pre-specified Age Group All participants 16 to 55 years	y of BNT162b2 Again vidence of Prior SAR: BNT162b2 N ^a = 18198 Cases n1 ^b Surveillance Time ^c (n2 ^a) 2.214 (1741)	s.Confirmed CO S.CoV-2 Infection Placebo N ^a =18325 Cases n ¹⁰ Surveillance Time ^c (n2 ⁰) (162) 2.222 (17511) 114	VID-19 From 7 - Evaluable Eff Efficacy % (95% Cl) 95.0 (90.3, 97.6) ^e 95.6	Days After fficacy Met Predefined Success Criterion* Yes NA	0.05% Pfiz 174 174	er 03 11 99.95%	0.93% No V 17	accine 349 511 99.079	
	1.234 (9897)	1.239 (9955)	(89.4, 98.6)						
> 55 years and older	3	48	93.7	NA					
10	0.980 (7500)	0.983 (7543)	(80.6, 98.8)			Observed	Expected	Marginal Row Totals	
-Success criterion: the posterior probability t	nat true vaccine efficacy > 3	0% conditioning on the	available data is >	99.5% at the final	Pfizer	17403 (17326.25) [0.34]	17249 (17325.75) [0.34]	34652	
^a N = number of participants in the specified	group.				Nothing	17349 (17425.75) [0.34]	17502 (17425.25) [0.34]	34851	
^b n1 = Number of participants meeting the er	ndpoint definition.				Marginal Column Totals	34752	34751	69503 (Grand Total)	
⁶ Total surveillance time in 1000 person-year endpoint. Time period for COVID-19 case as ^d n2 = Number of participants at risk for the e * Credible interval for VE was calculated usin ^f Confidence interval (CI) for VE is derived based and the surveillance of the surveillance of the surveillance of the surveillance of the surveillance of the surveillance of the surveillance of the surveillance of the surveillance of the surveillance of the surveillance of the surveillance of the surveillance of the surveillance of the surveillance o	The chi-square statistic is The chi-square statistic wi	1.3561. The p-value is .2442 th Yates correction is 1.3385	18 Not significant at $p < .05$ 6. The <i>p</i> -value is .247304. M	Dot significant at p < .05.					
Absolute Risk Reduction (ARR) = 0.93% minus 0.05%)=0.88%									

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 ⁿ th	nd Injection there wer e number of cases wa	re fewer cases of (Isn't statistically s	COVID but The D significant. <i>p=NS</i>	lifference in	0.08%		1.33%				
Table 17. Final Sched the Second Dose per Primary Endpoint: COVID-19 (per adjudication committee assessment)	Table 17. Final Scheduled Efficacy Analysis, Primary Endpoint COVID-19 Starting 14 Days After the Second Dose per Adjudication Committee Assessments, Per Protocol Set Vaccine Group Primary Endpoint: COVID-19 (per adjudication Control (Incidence Rate per (Incidence Rate per 1,000 person- 1,000 per										
All participants	(11)<0.1) 3.328	(185)(1.3) 56.510	94.1% (89.3%, 96.8%)	Yes		Observed	Expected	Marginal Row Totals			
18 to <65 years ¹	7/10551 (<0.1) 2.875	156/10521 (1.5) 64.625	95.6%; (90.6%, 97.9%)	NA	Moderna Nothing	13923 (13836) [0.55] 13698 (13785) [0.55]	13749 (13836) [0.55] 13872 (13785) [0.55]	27672 27570			
65 years and older ²	4/3583 (0.1); 4.595	29/3552 (0.8); 33.728	86.4%; (61.4%, 95.5%)	NA	Marginal Column Totals	27621	27621	55242 (Grand Total)			
Absolute R	lisk Reductio	on (ARR) =	1.33% min	us <mark>(0.08</mark> %	The chi-square statistic with 1.25%	th Yates correction is 2.167	1. The <i>p</i> -value is .140989. <i>I</i>	lot significant at <i>p</i> < .05.			

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-I	Days	Doe	s the	e Jan	ssen	Vac	cine <u>F</u>	Preve	<u>nt</u> C0	OVID?
	The	EUA Do	cument l	Results	Compari	ng Vacc	inated w	ith Non-V	accinated	d Individ	uals
	14 D Diffe	ays after the erence in the r	Injection the number of ca	re were few ses was sta	ver cases of Co tistically signi	OVID & The ficant. <i>p≤o.o</i>	5 5	0.81%		2.38%	
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*, Per Protocol Set Onset at Least (14 Days) Janssen (21460) Onset at Least (14 Days) Onset at Least 28 Days Baseline in Adde.CoV2.S Placebo Motion of the set of th								accine 1061 1574			
Sero Rega base	ardless of line SARS-	Person-vrs 176 21636 3450.2	Person-vrs 513 (21574) 3409.8	(95% CI) 66.1% (59.7, 71.6)	Person-yrs 114 (21424) 3436.3	Person-yrs 326 (21199) 3385.9	(95% CI) 65.5% (57.2, 72.4)		99.19%		97.62%
Posi	tive	3 (2122) 336.3	4 (2030) 320.8	28.5% (-322.8, 89.5)	1 (2118) 336.1	2 (2021) 320.0		Johnson & Johnson Nothing	Observed 21460 (21290.75) [1.35] 21061 (21230.25) [1.35]	Expected 21121 (21290.25) [1.35] 21399 (21229.75) [1.35]	Marginal Row Totals 42581 42460
Nega	ative Sponsor table	173 (19514) 3113.9 s GEFPE07A. GEF	509 (19544) 3089.1 PE07C	66.3% (59.9, 71.8)	113 (19306) 3100.3	324 (19178) 3065.9	65.5% (57.2, 72.4)	Marginal Column Totals	42521	42520	85041 (Grand Total)
N=Tota ^a Based ^b If few	al number of pa d on serological ver than 6 cases	rticipants at risk per I test at baseline are observed for an	category endpoint then the	VE is not shown				The chi-square statistic w	ith Yates correction is 5.3577	7. The <i>p</i> -value is .020631. S	ignificant at p < .05.
N.E	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 Doo	cument l	Results	Compari	ng Vacc	inated w	/ith Non-V	accinated	l Individu	als
	28 Days after the Injection there were fewer cases of COVID but The Difference was NO LONGER statistically significant. <i>p=NS</i>										
Table 14 Non-cer Baseline Baseline	l. Vaccin atrally Co SARS-C	e Efficacy of Fin onfirmed Cases, CoV-2 Status ^a , F Ons Ad26.COV2.S Cases (N)	rst Occurrence With Onset a Per Protocol S et at Least 14 Placebo Cases (N)	e of <u>Moderat</u> t Least 14 or et Days VF%	e to Severe/Crit at Least 28 Day Ons Ad26.COV2.S	ical COVID-19 ys After Vacci et at Leas Placebo Cases (N)	Including nation, by Days	Jans (213 (214	ssen 310 124	No Va 208 (211	ccine 73 99
Serosta Regardl baseline	ess of SARS-	Person-yrs 176 (21636) 3450.2	Person-yrs 513 (21574) 3409.8	(95% CI) 66.1% (59.7, 71.6)	Person-vrs 114 (21424) 3436.3	Person-vrs 326 21199 3385.9	(95% CI) 65.5% (57.2, 72.4)		99.47%		98.46%
Positive	iulus	3 (2122) 336.3	4 (2030) 320.8	28.5% (-322.8, 89.5)	1 (2118) 336.1	2 (2021) 320.0		Johnson & Johnson Nothing	Observed 21310 (21202.5) [0.55] 20873 (20980.5) [0.55]	Expected 21094 (21201.5) [0.55] 21087 (20979.5) [0.55]	Marginal Row Totals 42404 41960
173 (19514) 509 (19544) 66.3% 113 (19306) 324 (19178) 65.5% Negative 3113.9 3089.1 (59.9, 71.8) 3100.3 3065.9 (57.2, 72.4) Source: Sponsor tables GEFPE07A, GEFPE07C The chi-square statistic is 2.1916. The p-value is .13876 (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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