

COVID-19 VACCINE TRIALS

SUMMARY OF PFIZER AND MODERNA COVID-19 VACCINE RESULTS

Some of the most common concerns voiced involve the speed with which these vaccines were developed and whether they are safe or not. How were the companies able to get these vaccines developed and ready for distribution so fast? Were they tested in persons who are most vulnerable? Are the vaccines safe?

Even though COVID-19 vaccines were developed at an extraordinary speed, companies were required to take all of the regulatory and operational steps normally required for all vaccine trials, so none of these steps were skipped. What did occur that does not normally occur was some upfront financial assistance from the federal government (Moderna accepted, Pfizer declined) and federal regulatory agencies working closely with the companies, providing near real-time data with companies receiving review and advice more quickly. In addition, once Phase 1 trials were completed, companies began producing vaccines while Phase 4 trials were ongoing, so companies did not wait until trials were completed as is the usual norm.

Pfizer Vaccine, BNT162b2

Results of Phase 3 study of mRNA-based COVID-19 vaccine candidate, BNT162b2, met all of the study's primary efficacy endpoints. Analysis of the data indicates a vaccine efficacy rate of 95% ($p < 0.0001$) in participants without prior SARS-CoV-2 infection (first primary objective) and also in participants with prior SARS-CoV-2 infection (second primary objective), in each case measured from 7 days after the second dose.

The first primary objective analysis is based on 170 cases of COVID-19, as specified in the study protocol, of which 162 cases of COVID-19 were observed in the placebo group versus 8 cases in the BNT162b2 group. Efficacy was reported as consistent across age, gender, race and ethnicity demographics. The observed efficacy in adults over 65 years of age was over 94%.

There were 10 severe cases of COVID-19 observed in the trial, with nine of the cases occurring in the placebo group and one in the BNT162b2 vaccinated group.

A review of unblinded reactogenicity data from the final analysis which consisted of a randomized subset of at least 8,000 participants 18 years and older in the phase 2/3 study demonstrates that the vaccine was well tolerated, with most solicited adverse events resolving shortly after vaccination.

While the vaccine was well tolerated overall, and side effects lasted for only a day or two, persons taking the vaccine should be aware that the side effects are more than is seen in general for the flu vaccine and be prepared for them. Most side effects were mild to moderate and included injection-site pain, redness and swelling at the injection site, fatigue/tiredness, headache, chills, muscle pain, and joint pain. "Severe" side effects, defined as those that prevent persons from continuing daily activities were fatigue (3.8%), headache (2.0%), and a fever between 102.2°F to 104°F (less than 2.0%). The side effects above all occurred in study participants. In the UK, two healthcare workers experienced severe allergic reactions after taking the vaccine. Both had a history of severe allergic reactions and both have fully recovered.

The Phase 3 clinical trial of BNT162b2 began on July 27 and as of November 16, has enrolled 43,661 participants to date, 41,135 of whom have received a second dose of the vaccine candidate as of November 13, 2020. Approximately 42% of global participants and 30% of U.S. participants have racially and ethnically diverse backgrounds, and 41% of global and 45% of U.S. participants are 56-85 years of age. A breakdown of the diversity of clinical trial participants can be found [here](#) from approximately 150 clinical trials sites in United States, Germany, Turkey, South Africa, Brazil and Argentina. The trial will continue to collect efficacy and safety data in participants for an additional two years.

The actual participant diversity within U.S. participants consisted of 70% white, 10.1% Black, 13.1%



Hispanic/Latinx, 5.5% Asian, and 1.0% Native American. The observed efficacy of those over 65 years old—the age group with the highest risks from COVID-19—was over 94 percent. Older adults tended to report fewer and milder effects.

For demographic study details go to <https://www.pfizer.com/science/coronavirus/vaccine>.

Moderna Vaccine, mRNA-1273

Results of Phase 3 study of the mRNA-1273 vaccine candidate was co-developed by the Cambridge, Massachusetts-based biotechnology company Moderna, Inc., and the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health.

More than 30,000 participants enrolled at 100 clinical research sites in the United States. Recognizing the disproportionate impact of the epidemic on underrepresented minority populations, investigators worked with community engagement partners to enroll a diverse pool of participants. 37% of trial volunteers are from racial and ethnic minorities. Overall efficacy of vaccine, 94.5%.

The analysis comprised 95 cases of symptomatic COVID-19 among volunteers. Out of a total of 95 cases occurring, 90 of the cases occurred in the placebo group versus 5 cases which occurred in the vaccinated group. There were 11 cases of severe COVID-19 out of the 95 total cases, all of which occurred in the placebo group.

More than 7000 participants were over age 65 and more than 8000 were persons living with chronic diseases putting them at a higher risk of severe COVID-19; the study also included more than 11,000 people from communities of color broken down as follows; 63% White, 10% Black (3000+), 20% Hispanic/Latinx (6000+), 4% Asian and 3% All Others.

Moderna reported the following Grade 3 (severe) adverse reactions occurring greater than or equal to 2% after the first dose, injection site pain (2.7%) and after the second dose, fatigue (9.7%), myalgia (8.9%),

arthralgia (5.2%), headache (4.5%), pain (4.1%) and redness at the injection site (2.0%). In addition, less than 2.0% experienced high fevers between 102.2°F to 104°F.

For the demographic data and the study protocol details go to <https://www.modernatx.com/cove-study>

Conclusion:

While both studies provide a racial/ethnic and age breakdown, and the percentage of persons with conditions placing them at higher risk, the current information available does not appear to provide a further subgroup analysis of how each vaccine performed in each subgroup for adverse reactions, and efficacy. Both studies report that the side effects and efficacy were consistent across subgroups. While side effects are short-term, lasting for hours to a few days, they do occur and persons need to be aware and prepare for them.

The two studies demonstrate a diverse inclusion of racial and ethnic groups. Their success in doing this is noteworthy since this is often difficult to achieve. Both studies achieved a participation percentage of 10% with the 2030 estimated U.S. population percentage for Blacks/African Americans of 13.3%.

*U.S. Census Bureau
Estimate for 2030 U.S. Population
Numbers in the table are in "millions"*

White	248,503	76.9
Non-Hispanic White	197,970	61.3
Black or African American	43,001	13.3
American Indian and Alaska Native	4,055	1.3
Asian	18,319	5.7
Native Hawaiian and Other Pacific Islander	771	0.2
Two or More Races	8,480	2.5
Hispanic	57,470	17.8
Native-born population	279,283	100.0