

# 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 2/3 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, indicates a vaccine efficacy rate of 95%. Efficacy was reported as consistent across age, gender, race, and ethnicity.

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.

More than 43,000 people participated in the study. 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.

## **Moderna Vaccine, mRNA-1273**

The results of the study of the mRNA-1273 vaccine indicated a vaccine efficacy rate of 94.5% overall. More than 30,000 participants enrolled at 100 clinical research sites in the United States. 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.

Of the 30,000+ participants, more than 11,000 were 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 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.

## **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.

