# MYTHBUSTERS VACCINATION READY

## MYTH:

The COVID-19 Vaccine is not safe because it was developed and tested too rapidly

The mRNA COVID-19 vaccines followed a rigorous process similar to the standardized process for achieving FDA approval. Phase III trial data met specified safety and efficacy thresholds for authorization. The FDA advises ≥3000 participants to assess safety. Phase III trial data for Pfizer and Moderna vaccines had 30,000 − 50,000 participants over at least 8 weeks prior to authorization (most vaccine-related ADEs occur within 6 weeks).

**FACT:** 

There are 2 unbiased and independent advisory committees charged with evaluating proposed vaccines for safety and efficacy: (1) The Vaccine and Related Biological Products Advisory Committee (VRBPAC) that advises the FDA; (2) The Advisory Committee on Immunization Practices (ACIP) that advises the CDC. These committees are made up of experts vetted to avoid a conflict of interest and their decisions are made independent of financial and political considerations.

MYTH:

The COVID-19 Vaccine development process can't be trusted because it was politicized by the government and politicians

FACT:

## MYTH:

There is a high risk of severe and abnormal side effects

Vaccine-related side effects are usual undesired effects that accompany all vaccines to varying degrees. They may be consequent to administration (i.e., local redness, pain or swelling at the injection site) or an effect of the body's desired immune response (i.e., fever, malaise, etc). Phase III safety data showed these vaccines' side effect profiles to be largely mild, with side effects generally short-lived and resolving without further complication.

**FACT:** 

While mRNA technology is new in vaccine development, this technology has been successfully used in cancer treatments. There are multiple expert bodies that have reviewed the trial data to make official recommendations based on benefit vs. risk analysis. These committees, comprised of unbiased experts, have largely weighed in favor of the novel mRNA vaccines based on their safety and efficacy profiles.

MYTH:

Because mRNA vaccines are new we can't be confident in how safe they are

FACT:

# MYTH:

I should avoid the COVID-19 vaccine if I have an underlying medical condition

mRNA COVID-19 vaccines may be administered to people with underlying medical conditions provided they have not had a severe or immediate allergic reaction to any of the ingredients in the vaccine. Adults of any age with certain underlying medical conditions are at increased risk for severe illness from the virus that causes COVID-19. See the CDC's web page on Vaccination Considerations for Persons with Underlying Medical Conditions for more information.

FACT:

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COVID-19 vaccines will not give you COVID-19. None of the COVID-19 vaccines currently in development in the United States use the live virus that causes COVID-19. The goal for the vaccine is to teach our immune systems how to recognize and fight the virus that causes COVID-19. Sometimes these vaccines will prompt mild symptoms, such as fever, but these are normal and are a sign that the body is building immunity.

MYTH:

The COVID-19 Vaccine can give you COVID-19

**FACT:** 

### MYTH:

The COVID-19 vaccine guarantees that I cannot contract COVID-19

**Neither vaccine is 100% effective.** The current mRNA COVID-19 vaccines have demonstrated high efficacy (Pfizer – 95%; Moderna – 94.5%) in preventing the development of COVID-19 in COVID-19 negative individuals 7 and 14 days after the second dose, respectively. It will continue to be important for all individuals to continue to abide by respiratory hygiene and social distancing guidelines.

**FACT:** 

There is no element regarding the vaccine platform or clinical experience to-date suggestive of undue risk for long-term side effects. Historically, vaccine-related side effects generally occur within 6 weeks of administration, with severe anaphylaxis-type reactions typically occurring quickly (hours – days) after administration. Safety evaluations occurred 8 weeks post-administration. Like all drug products and biologics, Phase IV data will continue to be gathered to inform what is known regarding long-term side effects.

MYTH:

There are anticipated to be long-term side effects that we should be concerned about from getting the COVID-19 vaccine

FACT:

### MYTH:

The COVID-19 vaccine will alter my DNA

The COVID-19 vaccines are messenger RNA (mRNA) vaccines which instruct the body how to make protein and do not interact with DNA. mRNA vaccines work by instructing cells in the body how to make a protein that triggers an immune response. Injecting mRNA into your body will not interact or do anything to the DNA of your cells. Human cells break down and get rid of the mRNA soon after they have finished using the instructions.

FACT:

Due to the severe health risks associated and possible reinfection with COVID-19, you should be vaccinated regardless of whether you have already been exposed to or contracted COVID-19. The "natural immunity" gained from exposure to a pathogen varies from person to person. Both natural immunity and vaccine-induced immunity are important aspects of COVID-19 that experts are working to learn more about, and CDC will keep the public informed as new evidence becomes available.

MYTH:

Because I have already likely been exposed to COVID-19 I should not receive the vaccine

FACT:

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## MYTH:

The vaccine causes infertility in women &
it is unsafe for pregnant or lactating
women to receive the vaccine

The myth that COVID-19 vaccines cause infertility has been debunked. This proposed causality was erroneously made due to a structural similarity between syncitin-1 (a protein essential for placental integrity) and the SARS-CoV-2 spike protein that mRNA vaccines engender an immune response against. The American College of Obstetricians and Gynecologists (ACOG) has officially recommended immunizing pregnant and lactating women against COVID-19 based upon risks vs benefits. Additionally, the Society for Maternal-Fetal Medicine (SMFM), which provides education and advocacy for high-risk pregnant women and their babies, recommended COVID-19 vaccine administration to pregnant healthcare workers in their December 1, 2020 statement.

**FACT:** 

People with severe allergies NOT related to vaccines or injectable medications may still get vaccinated. People who have had an immediate allergic reaction to a vaccine or injectable medication should ask their doctor about getting the vaccine. Additional safety and observation considerations may be prudent. NOTE: The vaccines are not live-virus based nor do they contain eggs. The vaccinespecific ingredients are readily available in the respective EUAs (Section 13-Description) for individuals to assess against any potential allergies.

FACT:

### MYTH:

If I've had severe allergies or a reaction to other vaccines I should not receive a COVID-19 vaccine