

In early 2020, as the novel coronavirus spread rapidly across the globe, biopharmaceutical researchers turned to face the challenge head on. Given the pressing need for safe and effective vaccines to help prevent COVID-19, along with the volume of information that remains unknown about the disease, a [wide range of approaches](#) to vaccine development are under investigation to improve the odds that one or more of these approaches will be successful.

“By no means have the last few months been business as usual,” said Advait Badkar, Ph.D., Senior Director, Novel Delivery Technologies at Pfizer, which is one of numerous companies researching a potential COVID-19 vaccine. “We’ve all stepped up to meet this challenge.”

BREAKING BARRIERS WITH mRNA TECHNOLOGY

One of the approaches under investigation to developing a COVID-19 vaccine uses mRNA technology, which potentially offers greater flexibility and quicker development timelines than traditional vaccine development.

Unlike conventional [vaccines](#), which work by injecting an inactive or weakened pathogen, or part of a pathogen, into the body to generate an immune response, [mRNA vaccines](#) do not require viral material at all. Rather, based on information gleaned from sequencing viral genetic material, these vaccines use strands of mRNA to provide the human body with genetic instructions to produce a viral antigen, such as a protein.

Once injected, the mRNA enters cells, which manufacture the antigen and give the immune system the exposure it needs to build immunity, without actually causing an infection or exposing people to any form of the virus.

Compared to the conventional approach to vaccine development, mRNA vaccines [could require less time to advance](#). Currently, [it takes about a week](#) to produce an experimental batch of mRNA vaccine, compared to the months required by traditional vaccine manufacturing processes that rely on chicken eggs or mammalian cells. Scientists also [anticipate](#) that should an mRNA vaccine candidate prove successful, the production process could be rapidly scaled and standardized to accelerate distribution.

Building on prior work to develop an mRNA vaccine to help prevent other diseases, numerous companies have made progress identifying potential candidates against the novel coronavirus that causes COVID-19.

ENSURING SAFETY AND EFFECTIVENESS

Because mRNA vaccines do not use an inactivated virus, but rather a portion of the viral sequence encoding for one or more viral antigens, no virus is needed to make a batch of mRNA vaccine. Additionally, mRNA vaccines [have so far demonstrated a favorable safety profile](#) in preclinical studies.

Still, the human body is incredibly complex, and scientists cannot predict exactly how or if it will respond to a new experimental vaccine without clinical testing. That’s where Dr. Badkar and his team come in. As the head of Pfizer’s Novel Delivery Technologies (NDT) group, he helps guide the formulation and process development of vaccines through

clinical trials to commercial readiness. This includes the need to scale up manufacturing to produce large quantities of the potential vaccine.

Dr. Badkar also helps ensure adherence to strict quality and regulatory standards designed to protect patient safety and assure consistent product quality. Across the board, vaccines [undergo extensive testing](#) for safety and effectiveness prior to any regulatory approval. Once a vaccine is licensed, regulatory authorities and the vaccine sponsor routinely monitor its use and investigate any potential safety concerns.

RESPONDING TO A GLOBAL NEED

As the world continues to feel the impact of COVID-19, the biopharmaceutical industry is working around the clock to identify and develop safe and effective vaccines to prevent infection, while also researching and developing new ways to treat those infected with the virus.

“An incredible sense of urgency is at the forefront for me and my colleagues,” Dr. Badkar said. “Some of us have lost loved ones, and some of us have been directly impacted by the virus. We recognize the opportunity to work on a potential solution, which brings with it a huge responsibility.”